

NIH CONSENSUS DEVELOPMENT CONFERENCE ON
INTERVENTIONS TO PREVENT HIV RISK BEHAVIORS

Program and Abstracts
(Online Edition)

NIH Consensus Development Conference
February 11–13, 1997

Natcher Conference Center
National Institutes of Health
Bethesda, Maryland

Sponsored by the National Institute of Mental Health and the NIH Office of Medical Applications of Research; cosponsored by the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Aging, the National Institute on Drug Abuse, the National Institute of Nursing Research, the Office of AIDS Research, and the Office of Research on Women's Health, all of NIH; the Centers for Disease Control and Prevention; and the Health Resources and Services Administration.

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Contents

Introduction to the NIH Consensus Development Conference on Interventions To Prevent HIV Risk Behaviors	1
Agenda	4
Panel	7
Speakers	8
Planning Committee	10
Abstracts	12
Welcome and Introduction	
Contextual Overview of Presentations at Consensus Development Conference <i>Ellen Stover, Ph.D.</i>	13
I. Epidemiology of AIDS and HIV Infection and Risk Behaviors	
Epidemiology of AIDS: National and International Perspective <i>Helene D. Gayle, M.D., M.P.H.</i>	15
Epidemiology of HIV-Related Behaviors in Risk Populations <i>Lynda S. Doll, Ph.D.</i>	19
II. Design Issues in AIDS Prevention	
Reducing High-Risk HIV Behaviors: An Overview of Effective Approaches <i>Thomas J. Coates, Ph.D.</i>	24
Some Principles for Preventing HIV: Rigor and Reality in Study Design <i>Mervyn Susser, M.B., B.Ch., F.R.C.P.(E.), D.P.H.</i>	30
Theoretical Models of HIV Prevention <i>Martin Fishbein, Ph.D.</i>	33
Consequences of HIV Prevention Interventions and Programs: Spectrum, Selection, and Quality of Outcome Measures <i>David R. Holtgrave, Ph.D.</i>	37
III. Interventions To Reduce High-Risk Sexual and Substance Abuse Behaviors	
Behavioral Interventions With Gay and Bisexual Men and Youth <i>Jeffrey A. Kelly, Ph.D.</i>	41
Interventions To Reduce Heterosexual Transmission of HIV <i>Mary Jane Rotheram-Borus, Ph.D.</i>	45

Behavioral Interventions With Women <i>Anke A. Ehrhardt, Ph.D.</i>	51
Behavioral Interventions With Heterosexual Adolescents <i>John B. Jemmott III, Ph.D., and Loretta Sweet Jemmott, Ph.D., F.A.A.N.</i>	54
Community-Based Outreach Risk-Reduction Strategy To Prevent HIV Risk Behaviors in Out-of-Treatment Injection Drug Users <i>Richard H. Needle, Ph.D., and Susan Coyle, Ph.D.</i>	59
The Role of Needle Exchange Programs in HIV Prevention <i>David Vlahov, Ph.D.</i>	64
Drug Abuse Treatment as AIDS Prevention <i>David Metzger, Ph.D.</i>	70
International Epidemiology of HIV Among Injecting Drug Users <i>Don C. Des Jarlais, Ph.D.</i>	74
IV. International Perspective	
International Perspective on AIDS Prevention Research <i>Michael H. Merson, M.D.</i>	76

Introduction to the NIH Consensus Development Conference on Interventions To Prevent HIV Risk Behaviors

One in 250 people in the United States is infected with the human immunodeficiency virus (HIV), which causes AIDS; AIDS is the leading cause of death among men and women between the ages of 25 and 44. Every year, an additional 40,000 to 80,000 Americans become infected with HIV, mostly through behaviors that are preventable. In the United States, unsafe sexual behavior and drug abuse among gay men and men who have sex with men still account for the largest number of cases, but women are becoming infected at a rate higher than that of men. The percentage of AIDS cases caused by unsafe heterosexual contact increased by 21 percent from 1990 to 1991 and continues to escalate. In nearly one-third of Americans infected with HIV, injection drug use is a risk factor.

The purpose of this conference is to examine what is known about behavioral interventions that are effective with different populations in different settings for three modes of transmission: sexual behavior, substance abuse, and transmission from mother to child. Experts will also discuss the international and national epidemiology of HIV and the history of AIDS prevention efforts.

Research has led to significant progress in understanding how to help individuals change their AIDS-related risk behaviors. These interventions are based on a variety of models of behavior change, including social learning theory and related health and substance abuse models; they begin with AIDS and substance abuse education, but also include skill acquisition, assertiveness training, and behavioral reinforcement components. Recent research indicates that aggressive promotion of safer sexual behavior and prevention of substance abuse could avert tens of thousands of new HIV infections and potentially save millions of dollars in health care costs. To date, however, there has not been widespread agreement among health professionals as to which interventions are most effective in which settings and among which populations.

Behavioral interventions are currently the only effective way of slowing the spread of HIV infection. Vaccines selected for future trials may have modest or unknown efficacy, and therefore the trials will need to include behavioral interventions. Recommendations coming from this conference will have immediate implications for service delivery in health care settings, including substance abuse treatment programs; sexually transmitted disease clinics; inner-city health programs reaching disenfranchised high-risk women, men, and adolescents; and mental health programs that serve high-risk, chronically mentally ill people. Knowing which behavior change interventions are most effective will assist public health personnel in allocating energy and resources.

The conference will bring together behavioral and social scientists, prevention researchers, statisticians and research methodologists, clinicians, physicians, nurses, social workers, mental health professionals, other health care professionals, patients, and members of the public.

Following 1^{1/2} days of presentations and audience discussion, an independent, non-Federal consensus panel will weigh the scientific evidence and write a draft consensus statement that it will present to the audience on the third day. The consensus statement will address the following key questions:

- How can we identify the behaviors and contexts that place individuals/communities at risk for HIV?
- What individual-, group-, or community-based methods of intervention reduce behavioral risks?
- What are the benefits and risks of these procedures?
- Does a reduction in these behavioral risks lead to a reduction in HIV?
- How can risk-reduction procedures be implemented effectively?
- What research is most urgently needed?

In addition, the panel will consider how the conference recommendations can influence implementation of prevention programs throughout the public health system.

On the final day of the meeting, the conference and panel chairperson, David Reiss, M.D., Professor and Director, Division of Research, Department of Psychiatry, George Washington University Medical Center, will read the draft statement to the conference audience and invite comments and questions. A press conference will follow to allow the panel and chairperson to respond to questions from media representatives.

GENERAL INFORMATION

Conference sessions will be held in the Natcher Conference Center (Building 45), NIH, 9000 Rockville Pike, Bethesda, Maryland. Sessions will run from 8:30 a.m. to 4:30 p.m. on Tuesday, 8:30 a.m. to 12:30 p.m. on Wednesday, and 9 to 11 a.m. on Thursday. The telephone number for the message center is 301-496-9966.

CAFETERIA

The cafeteria is located on the lobby level and is open daily from 7:00 a.m. to 3:00 p.m.

CONTINUING EDUCATION CREDIT

For Physicians

The purpose of this Consensus Development Conference is to examine what is known about behavioral interventions that are effective with different populations in different settings for three modes of transmission: sexual behavior, substance abuse, and transmission from mother to child. Experts will also discuss the international and national epidemiology of HIV and the history of AIDS prevention efforts.

The conference will (1) present in open, public sessions state-of-the-art information regarding interventions to prevent HIV risk behaviors, (2) prepare a statement in response to the five specific questions, and (3) inform the biomedical research and clinical practice communities and the general public of the conclusions and recommendations of the panel.

The National Institutes of Health is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The National Institutes of Health designates this continuing medical education activity for a maximum of 13 hours in Category 1 credit toward the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit he/she actually spent in the educational activity.

For Psychologists

An application has been filed with the American Psychological Association to obtain continuing education accreditation for this conference.

SPONSORS

The primary sponsors of this conference are the National Institute of Mental Health and the NIH Office of Medical Applications of Research. The conference is cosponsored by the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Aging, the National Institute on Drug Abuse, the National Institute of Nursing Research, the Office of AIDS Research, and the Office of Research on Women's Health, all of NIH; the Centers for Disease Control and Prevention; and the Health Resources and Services Administration. This is the 104th Consensus Development Conference held by the NIH since the establishment of the Consensus Development Program in 1977.

Agenda

Tuesday, February 11, 1997

8:30 a.m.	Welcome and Introduction	Steven E. Hyman, M.D. Director, National Institute of Mental Health
		Ellen Stover, Ph.D. Director, Office on AIDS National Institute of Mental Health
8:45 a.m.	Charge to the Panel	John H. Ferguson, M.D. Director, Office of Medical Applications of Research
8:55 a.m.	Overview of Conference	David Reiss, M.D. Conference and Panel Chairperson
	I. Epidemiology of AIDS and HIV Infection and Risk Behaviors	
9:05 a.m.	Epidemiology of AIDS: National and International Perspective	Helene D. Gayle, M.D., M.P.H.
9:25 a.m.	Epidemiology of HIV-Related Behaviors in Risk Populations	Lynda S. Doll, Ph.D.
9:45 a.m.	Discussion	
	II. Design Issues in AIDS Prevention	
10:00 a.m.	Reducing High-Risk HIV Behaviors: An Overview of Effective Approaches	Thomas J. Coates, Ph.D.
10:20 a.m.	Some Principles for Preventing HIV: Rigor and Reality in Study Design	Mervyn Susser, M.B., B.Ch., F.R.C.P.(E.), D.P.H.
10:40 a.m.	Discussion	
11:00 a.m.	Theoretical Models of HIV Prevention	Martin Fishbein, Ph.D.

Tuesday, February 11, 1997 (continued)

11:20 a.m. Consequences of HIV Prevention Interventions and David R. Holtgrave, Ph.D.
Programs: Spectrum, Selection, and Quality of
Outcome Measures

11:40 a.m. Discussion

12:15 p.m. Lunch

**III. Interventions To Reduce High-Risk Sexual
and Substance Abuse Behaviors**

1:30 p.m. Behavioral Interventions With Gay and Bisexual Men Jeffrey A. Kelly, Ph.D.
and Youth

1:50 p.m. Interventions To Reduce Heterosexual Transmission Mary Jane Rotheram-Borus,
of HIV Ph.D.

2:10 p.m. Behavioral Interventions With Women Anke A. Ehrhardt, Ph.D.

2:30 p.m. Discussion

3:00 p.m. Behavioral Interventions With Heterosexual John B. Jemmott III, Ph.D.
Adolescents

3:30 p.m. Discussion

4:30 p.m. Adjournment until Wednesday

Wednesday, February 12, 1997

8:30 a.m. Community-Based Outreach Risk-Reduction Strategy Richard H. Needle, Ph.D.,
To Prevent HIV Risk Behaviors in M.P.H.
Out-of-Treatment Injection Drug Users

8:50 a.m. The Role of Needle Exchange Programs in HIV David Vlahov, Ph.D.
Prevention

9:05 a.m. Drug Abuse Treatment as AIDS Prevention David Metzger, Ph.D.

9:20 a.m. International Epidemiology of HIV Among Injecting Don C. Des Jarlais, Ph.D.
Drug Users

9:40 a.m. Discussion

Wednesday, February 12, 1997 (continued)

IV. International Perspective

10:10 a.m.	International Perspective on AIDS Prevention Research	Michael H. Merson, M.D.
10:35 a.m.	Discussion	
11:00 a.m.	Public Statements	
12:30 p.m.	Adjournment until Thursday	

Thursday, February 13, 1997

9:00 a.m.	Presentation of the Consensus Statement	David Reiss, M.D. Panel and Conference Chairperson
9:30 a.m.	Discussion	
11:00 a.m.	Panel Meets in Executive Session	
1:00 p.m.	Press Conference	
2:00 p.m.	Adjournment	

Panel

Panel and Conference

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Abstracts

The following abstracts of presentations to the NIH Consensus Development Conference on Interventions To Prevent HIV Risk Behaviors were furnished by presenters in advance of the conference. This book is designed for the use of panelists and participants in the conference and as a reference document for anyone interested in the conference deliberations. We are grateful to the authors who have summarized their materials and made them available in a timely fashion.

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Contextual Overview of Presentations at Consensus Development Conference

Ellen Stover, Ph.D.

Introduction to the Conference

Prevention remains a critical priority even though HIV therapies are improving and combinations of drugs are prolonging life. HIV prevention is both more humane and more cost-effective than treatment for HIV/AIDS. The AIDS epidemic is taking lives prematurely and tragically, and because youth are at risk, years of productivity are lost. In the United States, more men and women between the ages of 25 and 44 die from AIDS than from other diseases. The epidemic is changing and expanding into more diverse populations.

Beginning in 1983, knowledge increased about the risk behaviors people engage in that transmit HIV (Turner, Miller, & Moses, 1989). Researchers and others learned quickly how to study the illegal behaviors and the stigmatized sexual behaviors that transmit HIV, determine the prevalence and incidence of these behaviors and their determinants in various populations, and develop and test interventions to reduce risk for HIV infection (Auerbach, Wypijewska, & Brodie, 1994). These behaviors include unprotected sexual intercourse with an infected partner and use of contaminated drug injection equipment.

Converging evidence from the studies that will be presented at this conference demonstrate that combinations of scientifically rigorous, theoretically based, tailored interventions have reduced behaviors that transmit HIV in many different populations (Miller, Turner, & Moses, 1993).

Overview of Presentations

This conference has four sessions. The opening talks by Drs. Gayle and Doll review the modes of transmission, the areas and populations most affected, the epidemiology of HIV infection, and the distribution of risky sexual and drug-using behaviors in U.S. populations.

The next four talks by Drs. Coates, Susser, Fishbein, and Holtgrave provide a context for the conference. Dr. Coates will discuss five levels of intervention and the power of combining interventions at different levels. HIV prevention requires efforts at the level of the individual, the couple and family, the community, and the law and policy. Dr. Susser will analyze research designs needed to prove efficacy. Internal validity is valuable but must be balanced against the demands of external validity. Dr. Fishbein will discuss the behaviors that are responsive to interventions and the theoretical factors essential to behavior change. Behavior change also depends on factors such as the prevalence of HIV in the area. Unlike a drug trial in which a pill is available and ready to test, trials of behavioral interventions must be tailored to the culture or gender of the targeted group. Finally, Dr. Holtgrave will demonstrate the reliability and validity of self-reports of behaviors and provide the linkage between self-reported behavior change and the prevention of the spread of HIV infection.

Intervention Presentations

Eight speakers will discuss HIV prevention interventions and under what conditions such interventions work for men who have sex with men, heterosexual men and women, women, adolescents, and injection drug users. Dr. Kelly will discuss interventions that work for men who have sex with men

and gay/bisexual youth. His presentation will focus on successful changes that have been sustained and documented for older gay men in specific communities.

Dr. Rotheram-Borus will review interventions for heterosexual men and women. The efficacy of prevention of HIV transmission via heterosexual intercourse has been demonstrated in a series of studies of high-risk populations. Almost no programs have been tailored for interventions with heterosexual men as they have been for women. Dr. Ehrhardt will review studies of interventions for women, which show that interventions must be gender-specific. New protection methods are needed that are under a woman's control. Dr. Ehrhardt's review highlights issues of HIV, sexually transmitted disease, and family planning that are intimately involved in a woman's choice of protection. Dr. Jemmott will review community and school-based interventions with adolescents. Youth are initiating sexual activity at a younger age, and they are increasingly at risk for HIV. Dr. Jemmott's emphasis is on ethnic minority school-age adolescents.

Compelling evidence that seroincidence in injection drug users can be reduced when harm reduction programs and community outreach activities are rigorously implemented while seroprevalence is low will be presented. Dr. Needle will present data from multisite trials demonstrating the effectiveness of outreach and community interventions. Dr. Vlahov will document the effectiveness of needle exchange programs in preventing HIV seroincidence. The effectiveness of drug abuse treatment in reducing seroincidence will be reviewed by Dr. Metzger. Dr. Des Jarlais will review the epidemiology of HIV and drug use in the United States and abroad, and, in the final session, Dr. Merson will review the international experience with HIV prevention, focusing on interventions to prevent sexual transmission and the barriers that must be overcome to implement effective programs. Dr. Merson will also make a closing statement.

Recommendations from the Conference

Following each session, the panel will be able to ask questions about future directions and what steps are necessary to implement specific recommendations. The consensus statement that the panel prepares can be an important part of the process to implement the best possible HIV prevention research in the public health system. This process will enable us to more effectively reach the public and have an impact on AIDS prevention programs and policies (Jonsen & Stryker, 1993).

References

Auerbach, J. D., Wypijewska, C., & Brodie, K. H. (Eds.). (1994). *AIDS and behavior: An integrated approach*. Washington, DC: National Academy Press.

Jonsen, A. R., & Stryker, J. (Eds.). (1993). *The social impact of AIDS in the United States*. Washington, DC: National Academy Press.

Miller, H. G., Turner, G. G., & Moses, L. E. (Eds.). (1993). *AIDS: The second decade*. Washington, DC: National Academy Press.

Turner, C. F., Miller, H. G., & Moses, L. E. (Eds.). (1989). *AIDS: Sexual behavior and intravenous drug use*. Washington, DC: National Academy Press.

Epidemiology of HIV Infection and AIDS: National and International Perspective

Helene D. Gayle, M.D., M.P.H.

Introduction

Spreading unnoticed since the late 1970s, AIDS was not recognized until 1981 when the Centers for Disease Control (CDC) published an article in *Morbidity and Mortality Weekly Report* describing unusual clusters of opportunistic diseases among young gay men in New York and California. Today, the HIV pandemic is made up of multiple subepidemics in different regions and populations of the world, each with fairly unique epidemiologic, sociodemographic, behavioral, and biologic factors contributing to the spread of infection. However, the pandemic has demonstrated certain general trends: people in the prime of life are most affected; as the epidemic matures, people become infected with HIV at younger ages; women are at greater risk from heterosexual transmission than men; and, over time, the epidemic moves from the original high-risk groups into a broader cross-section of society.

Conclusions

Because people are becoming infected with HIV at earlier ages, prevention activities of the future must be targeted to young people (especially gay and racial/ethnic minority youth) and sustained over time, with early emphasis on preventing the initiation of sexual behaviors and drug use.

Current Trends

According to estimates of the global HIV/AIDS situation as of mid-1996 made by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO), nearly 30 million adults and children have been infected with HIV since the beginning of the pandemic; approximately 22 million are living with HIV infection or AIDS; and more than 8,500 people become infected each day—7,500 adults and 1,000 children. Additionally, about 4.5 million adults and 1.3 million children have already died. Although HIV transmission is now occurring in every country, national prevalence average estimates among adults vary widely throughout the world, from an estimated 1 per 100,000 people (0.0001 percent) in the Central Asian Republics and the Democratic People's Republic of Korea, to more than 10 percent of the population in five African countries.

UNAIDS/WHO estimate that 75–85 percent of HIV infections in adults around the world were acquired through unprotected sexual intercourse, with 70 percent resulting from heterosexual intercourse. Five to 10 percent are thought to be a result of sharing drug injection equipment with an infected person, although this percentage is growing—and in many areas, it is the dominant mode of transmission. An additional 3–5 percent of worldwide infections are believed to have resulted from transfusion of HIV-infected blood or blood products.

Among the world's infants and children, more than 90 percent of all HIV infections were acquired from their mothers before or during birth or through breastfeeding. About 25–35 percent of HIV-infected mothers transmit HIV to their newborns. Studies in industrialized countries have shown that this transmission risk can be reduced by up to two-thirds with zidovudine therapy for HIV-infected pregnant women and their babies, but the recommended course of treatment is expensive and difficult to deliver, making it inaccessible to most of the world's HIV-infected women.

International Overview by Region

Africa

According to UNAIDS/WHO, an estimated 13.3 million adults are infected with HIV, representing about three-fifths of the world's total. An average of 5 percent of the adult population is believed to be infected with HIV, and because it is mostly heterosexually acquired, slightly more than one-half of them are women. Sub-Saharan Africa also has more children infected with HIV/AIDS than any other region of the world.

Asia

UNAIDS/WHO estimate that more than 4.7 million adults in Asia are living with HIV infection. Because the region is so populous, it now accounts for more than one-fifth of the world's total number of HIV infections. Drug injection practices and the commercial sex industry are significant contributing factors to HIV transmission in this region.

Latin America and the Caribbean

As in the United States, the first groups affected were homosexual and bisexual men. Today, UNAIDS/WHO estimate that almost 1.3 million adults there are HIV-infected. As the epidemic matures, more and more cases are being attributed to heterosexual intercourse and the sharing of equipment used to inject drugs. In the Caribbean region, heterosexual transmission has been the predominant transmission mode since the beginning of the epidemic, and more than 40 percent of all HIV-infected adults in this area are women. Although the region accounts for only 1 percent of the world's total number of HIV infections, adult prevalence there is second only to that of sub-Saharan Africa.

Europe

Adult HIV prevalence in the region averages substantially under 1 percent, but the dynamics of the epidemic differ in different parts of the continent. In the industrialized countries of western and northern Europe, homosexual transmission was the predominant mode of HIV transmission in the early 1980s. Today, drug injection practices and heterosexual intercourse are accounting for growing proportions of reported cases. In southern Europe, substance abuse and heterosexual transmission play a larger role. In eastern Europe, there is evidence of a rapidly spreading epidemic, fueled originally by nosocomial transmission and more recently by drug injection practices, especially in Poland and the Ukraine.

U.S. Overview

HIV/AIDS is now the number one cause of death for Americans between the ages of 25 and 44, and the sixth leading cause of death for young people aged 15–24. CDC has estimated that 650,000 to 950,000 persons, or approximately 0.3 percent of U.S. residents, are infected with HIV. The rates are higher among men than among women, and significantly higher among racial and ethnic minority populations, especially blacks.

Numerous seroprevalence surveys have provided valuable data to support the following estimates. The Survey of Childbearing Women was used between 1988 and 1994 to estimate the prevalence of HIV infection among women giving birth to live infants. In 1994, the survey included 2.7 million of the approximately 4.0 million births occurring that year and showed that an average of 0.16 percent (1.6 per 1,000 childbearing women) were infected with HIV. Prevalence varies substantially by geographic region and race/ethnicity, with the highest rates found in the South and Northeast. In 17 states that collected racial/ethnic information, prevalence rates were 5–30 times higher among black than white women, and generally higher among Hispanic than white women, especially in the Northeast.

Since 1987, approximately 60,000 Job Corps entrants have been screened each year for HIV. Between 1988 and 1992, these young people (aged 16–21) showed an average seroprevalence rate of 0.3 percent (3 per 1,000 youths). However, seroprevalence among males has steadily decreased, whereas among females it increased notably from 1988 through 1990 and then remained relatively stable through 1992. Seroprevalences were higher among blacks and Hispanics than among whites. In 1991 and 1992, average seroprevalence was lower among males (0.23 percent) than among females (0.35 percent), reflecting the impact of heterosexual transmission.

Recent serosurveys conducted among young gay men show that HIV prevalence is very high compared with the general population of U.S. youth. As of January 1996, surveys conducted in six urban counties in California, Texas, and Florida showed an average seroprevalence of 7 percent, with a range of 5–9 percent. Median HIV prevalence varied by age and race/ethnicity, with higher rates noted among survey participants 20–22 years of age (6–11 percent) and blacks (8–13 percent).

Looking carefully at reported AIDS cases in the United States also reveals significant trends. Nearly 550,000 AIDS cases were reported to CDC through June 1996, and more than 340,000 people of all ages have died. Surveillance data show that the epidemic is growing fastest among persons infected heterosexually and those who inject drugs. Cumulatively, the largest number and proportion of cases to date have occurred among gay and bisexual men, although recent years have seen a leveling in the number of cases reported from this population. In 1995, women accounted for the highest annual proportion of AIDS cases ever reported among adult and adolescent women in this country—19 percent.

For all transmission modes, even though the rates of reported AIDS cases per 100,000 population were (and are) highest in the Northeast, the largest numbers of cases are now being reported from the South. Increasing numbers of AIDS cases also are being reported from smaller metropolitan statistical areas (under 500,000 population) and rural areas. Geographic trends are very apparent when AIDS cases associated with drug injection are examined, including cases diagnosed among injection drug users (IDUs) themselves, their heterosexual sex partners, and children whose mothers either injected drugs or were the sex partners of IDUs. The Northeast region of the United States is most heavily affected by IDU-related HIV transmission—in 1995, nearly half (44 percent) of all IDU-related AIDS cases in the country were reported from this region. In contrast, IDU-associated cases accounted for only 13 percent of all reported AIDS cases from the West, where most AIDS cases continue to be reported among men who have sex with men.

Because of the 1993 change in the AIDS surveillance case definition that added persons with severe immunosuppression who have not yet developed an opportunistic infection (OI), CDC has had to develop special methods to examine trends over time in reported AIDS cases using estimates of the expected time to development of OIs. Recent trends in estimated AIDS-OIs show an overall slowing in the growth of the AIDS epidemic, as well as the following:

- Slight increases in the number of estimated AIDS-OIs.
- Increases among women and IDUs and through heterosexual transmission.
- Leveling among men who have sex with men.
- Leveling in the West, but continued increases in other geographic areas.
- Leveling among whites, but continued increases among blacks and Hispanics.
- Declines among children less than 13 years of age.

Observed slowing in the overall AIDS case rate and declines among certain groups clearly reflect the impact of successful prevention interventions. With sustained prevention efforts, these trends can be expected to continue in the near future. However, these overall trends at the national level mask local trends in the diverse subepidemics across the country and highlight the need for local and group-specific data that allow for appropriate targeting of prevention efforts.

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Epidemiology of HIV-Related Behaviors in Risk Populations

Lynda S. Doll, Ph.D.

Introduction

Since behavioral risk factors for HIV transmission were first identified, researchers have conducted surveys to assess the prevalence of these behaviors over time in populations thought to be at highest risk for HIV. National probability surveys have also been conducted providing periodic snapshots of risk levels in the general population. Together, these surveys provide an incomplete, yet important tool for evaluating the overall effectiveness of primary prevention efforts in the United States.

Scientific studies have identified risk behaviors that place persons at highest risk for HIV transmission, key of which are unprotected vaginal and anal intercourse and the use of nonsterile injection equipment. Other behaviors or environmental factors are important because they may increase the probability of exposure to the virus, facilitate transmission, or provide a trigger or context for risk (or protective) behaviors. Examples of these include contact with multiple sexual partners, the presence of sexually transmitted diseases (STDs), early initiation of sexual behavior, and the excessive use of alcohol and stimulants that impair judgment.

The goals of this presentation are to: (1) describe the prevalence of risk (and protective) behaviors among selected populations in the United States; (2) describe these data for age, gender, and racial/ethnic subgroups; and (3) describe changes in behaviors over time. Among the data sources to be used are national probability surveys; cohort studies, which are primarily of white gay men from urban areas; and cross-sectional surveys of selected populations. There are characteristics of these data sources, however, that should be considered when assessing and generalizing from these trends. Surveys, whether local or national, have primarily been conducted at a single point in time, with relatively small sample sizes, and with a limited set of items that have not been standardized across surveys. Cohort studies and cross-sectional surveys often, but not always, focus on convenience samples in selected urban locations of persons who are HIV-infected or at higher risk for HIV.

Conclusions

- HIV-related risk behaviors have been reduced in most populations, but subgroups are still engaging in high-risk behaviors, for example, younger persons and persons of color.
- Among some persons, for example, gay men, it has been difficult to maintain safer behavior over time.
- Condom use is higher with secondary partners than primary partners; in fact, persons report that it is easier to initiate low-risk behaviors with new partners than with established ones.
- Some studies have shown that increased condom use is more likely to have occurred among African-American men, who are also more likely to report risk behaviors.
- Heterosexual women who are monogamous may be at risk because of partners who are engaging in high-risk behaviors
- Among in-school youth, previously increasing rates of sexual experience have stabilized and condom use at last intercourse has increased.

- In-treatment IDUs engage in substantially lower rates of risk behaviors than injecting drug users (IDUs) not in treatment.

Current Trends in HIV-Related Risk Behaviors

Men Who Have Sex with Men (MSM)

Among men who have sex with men (MSM), behavior changes have been dramatic (Morris & Dean, 1994; Valleroy et al., 1996). For example, results from the National AIDS Behavioral Survey (NABS), a probability survey conducted in 1990–91 in high prevalence urban areas in the United States showed that, among 190 men reporting same gender contact, 24 percent reported no partners in the last year; 41 percent, a single partner; and 35 percent, two or more partners (Binson et al., 1995). Among men with two or more partners themselves or men with a partner at higher risk, nearly 70 percent reported consistent condom use in the last year. However, maintenance of those behaviors over time may be a challenge for some men and in particular for certain subgroups of the MSM population—youth and men of color. Two populations of MSMs that may be at higher risk for HIV transmission are youth and men of color (Adib et al., 1990; Ekstrand & Coates, 1990). In a recent study of young men ages 15–22 who were recruited from street venues in six urban areas, 39 percent of them reported unprotected anal sex in the last 6 months (Valleroy, 1996). More than 50 percent of African-American men ages 18 years and older interviewed in the California Bay area during a 6-month period from 1989 through 1990 reported unprotected anal sex with male partners, though 39 percent also reported condom use with anal sex (Petersen et al., 1992). Rates for risk behaviors (unprotected anal sex with male partners) have been shown to be high among Latino MSM and Asian Pacific Islanders, although not typically as high as rates for African-American men.

Heterosexual Men and Women

Most heterosexual men and women are at relatively low risk, although those at higher risk use condoms infrequently and inconsistently. In a nationally representative survey among heterosexual men and women at risk for HIV, only 11 percent used condoms consistently in 1990 and only 20 percent in 1992 (Choi & Catania, 1996). Through 1992, increases in condom use occurred primarily among men, persons in their thirties, and persons of color (Catania et al., 1995).

For heterosexual women who are at higher risk, this risk may be primarily through their male partners' sexual or drug use behaviors. One phenomenon noted in most of the populations studied is the trend for condom use to be adopted at a higher rate with secondary partners than with primary partners (Grinstead et al., 1993; Sikkema et al., 1996). Data from one 1990–91 study show that among persons with multiple partners in the last year, 18 percent of men and 22 percent of women reported consistent condom use with primary partners. Higher percentages reported use with secondary partners (Dolcini et al., 1993). More than 50 percent never used condoms at all.

Youth

Nationally representative studies of in-school youth, grades 9–12, show a stabilization in the number of youth reporting any sexual experience and a promising increase in condom use (Collins, 1996). Among in-school adolescents, rates of sexual experience appear to have stabilized at about 45 percent, and condom use has also increased to about 54 percent use at last intercourse (Kann et al., 1996). Young men and adolescents of color have higher risk levels; however, both groups also report higher levels of condom use (Fullilove et al., 1993). Of particular concern are the decreasing rates of condom use across grades, perhaps attributable to the development of primary relationships among students. Adolescents who are out of school, living on the street, or using illicit substances appear to have higher risk levels (Anderson et al., 1994).

Injecting Drug Users (IDUs)

For injecting drug users (IDUs), substantial decreases in sharing of needles and the use of nonsterile injection equipment have been reported in most urban settings in which surveys have been conducted (Battjes et al., 1995). Concomitant increases in condom use have been much slower (Des Jarlais et al., 1994; Friedman et al., 1993; Watters, 1994). In a recent comparison of IDUs recruited from treatment and street settings in three cities, in-treatment IDUs were 40 percent more likely to use new needles (Prevots & Monterroso, 1995).

Future Directions

Just as the virus mutates, the risk behaviors among different subpopulations are changing. It is therefore essential that behavioral epidemiologic studies continue to track the distribution of HIV-related risk behaviors among different populations. While large-scale national probability surveys are important to document overall trends, smaller focused surveys in high seroprevalence areas can focus AIDS prevention efforts.

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Reducing High-Risk HIV Behaviors: An Overview of Effective Approaches

Thomas J. Coates, Ph.D.

Introduction

HIV is preventable. Early in the epidemic, it was known that HIV was transmitted from an infected to uninfected individual through sexual intercourse and injection of infected blood, and from an infected mother to her fetus. Many personal, social, and health problems in the world would be averted if individuals were able to put knowledge into action. Such knowledge is an important armament against this lethal virus, but, sadly, such knowledge is not sufficient to protect people from HIV.

Conclusions

HIV may continue to spread but it is not because of lack of know-how. Prevention science and practice have yielded strategies that can decrease new HIV infections (Stryker et al., 1995).

- Knowledge is necessary but not sufficient to change high-risk HIV behavior.
- People can change and sustain high-risk HIV behaviors when they participate in effective AIDS prevention programs.
- Interventions at many levels are needed for AIDS prevention programs to be effective.
- Interventions at different levels act in combination; for example:
 - An individual intervention provides an individual with AIDS prevention skills and the motivation for their use;
 - A dyadic intervention can teach the couple how to negotiate the use of those prevention skills;
 - A community intervention can change the social norms of the group so that individual decisions to be safe can be encouraged and reinforced; and
 - A policy change can provide easy and legal access to the resources to be safe (sterile needles and/or condoms) when needed.

Reduction of Risk Behaviors: Interventions at Six Levels

This perspective recognizes that HIV transmission is caused, as are most health problems, by processes at the individual and societal levels, all of which affect individual behaviors and rates of transmission (Coates et al., 1996; Coates et al., 1997; Lurie et al., 1993; Stryker et al., 1995). Sweat and Dennison (1995) identified four levels of causation, and two additional levels have been added here. This six-level expanded model offers an excellent starting point for considering numerous strategies for reducing HIV transmission. Each level refers to specific determinants of risky behavior, as well as to a variety of strategies for changing high-risk behavior. The six levels of causation and change are the individual, dyadic/familial, institutional/community, policy/legal, superstructural, and medical/technological. Table 1 presents hypothesized mechanisms of action, and Table 2 presents potential change strategies.

Level	Definition	Examples
Individual	How the environment is experienced and acted upon by individuals; individual biological states	Knowledge, risk perception, self-efficacy, levels of intoxication, biological determinants of sexual behavior, etc.
Dyadic/Familial	How couples interact and negotiate sexual and needle-sharing behavior; how families communicate regarding sexual behavior	Implicit and explicit "rules" governing power and sexual relations
Institutional/Community	Social norms, resources, and opportunities; disease prevalence	Access to condoms and needles; health care behavior and norms of peers
Policy/Legal	Laws and policies	Paraphernalia laws, discriminatory practices, inheritance laws, laws and policies regarding confidentiality
Superstructural	Social and economic structures; widely held and pervasive societal customs and attitudes	Social and economic restraints on women
Medical/Technological	Medical, mental health, and drug treatment	Treatments for drug abuse and dependence, STDs, mental illness, and HIV; antenatal treatment; testing of blood donations; virucides and spermicides

Adapted from Sweat & Dennison (1995)

Interventions at the *individual level* help individuals to change by providing knowledge, or attempting to alter beliefs, attitudes, perceived norms, motivation, skills, or biological states related to high-risk activities. Interventions at the individual level attempt to change intrapsychic factors such as knowledge, skills, and motivations to use both knowledge and skills. Interventions at the individual level also attempt to assist individuals in reducing use of drugs related to high-risk activities. Examples abound of individual and small-group strategies aimed at modifying individual-level variables to modify sexual and drug injection behaviors to reduce HIV transmission. Many studies at this level will be presented in the talks to follow by Drs. Kelly, Rotheram-Borus, Ehrhardt, Jemmott, and Metzger.

Level	Change Mechanism	Intervention
Individual	Educational, motivational appeals, skills-building, counseling	Individual or small group strategies; drug and alcohol treatment
Dyadic/Familial	Skills-building, couples counseling with or without testing	Couples counseling and testing, family skills training
Institutional/Community	Community organization and mobilization, condom marketing and distribution, syringe distribution, access to care	Peer outreach, community mobilization, condom marketing and distribution, syringe exchange, drug and alcohol treatment on demand
Policy/Legal	Legislation and policy reform	Legislating syringe exchange and anti-discrimination laws, anonymous testing, changing laws and initiating movements
Superstructural	Social movements, revolution	Antipoverty programs, antidiscrimination programs, educational opportunity programs
Medical/Technological	Treatment can reduce high-risk behavior or the likelihood of engaging in it	Drug treatment, STD treatment, antenatal care, virucides and microbicides

Adapted from Sweat & Dennison (1995)

Interventions at the *institutional/community level* attempt to modify social norms and to influence social networking, resources and opportunities, and barriers to preventive practices in the community. Examples of change strategies include peer outreach, diffusion of innovation, community mobilization, mass media, condom marketing, and syringe exchange. Later presentations will describe many of these interventions including peer outreach and community mobilization (Drs. Kelly and Needle), syringe exchange (Drs. Des Jarlais and Vlahov), and the use of the media and marketing strategies to sell condoms (Dr. Merson).

The next level is the *dyadic/familial level*, which refers to interpersonal processes occurring between two individuals likely to have sexual intercourse or to share injection equipment. This level also refers to familial interactions likely to affect the course of HIV transmission. An example would be parent/child communication about sexuality. Interventions at the dyadic level attempt to influence the couple as a unit, whether providing them with strategies to reduce unprotected intercourse or to avoid sharing injection equipment with potentially infected partners. Dr. Rotheram-Borus will present the few studies that are conducted with couples.

Interventions at the *policy/legal level* attempt to influence laws, policies, and deep and abiding cultural norms. Legislative and policy changes are at the heart of changes at this level. Access to clean needles is an important and effective policy issue to reduce HIV transmission. Examples from other fields of disease prevention have documented the potency of changes at this level. Taxing cigarettes to reduce consumption, outlawing smoking in workplaces, requiring head protection for motorcycle riders, fluoridating water to reduce cavities, and increasing penalties for driving while under the influence of alcohol all have had a documentable and important impact on risk behaviors and disease prevention.

Interventions at the *superstructural level* attempt to identify and change deep and pervasive attitudes and structures in society that facilitate HIV transmission. Examples include sex phobia, homophobia, racism, acceptance of social and economic inequality, and sexism. Change strategies at the superstructural level include social movements, changes in constitutions of governing countries (the fact that the constitution of South Africa outlaws discrimination based on sexual orientation is important),

legislative changes, and revolutions. Such changes take a long time, and modification of such deep structures is not easy; nonetheless, consideration of possibilities should be undertaken in a comprehensive HIV prevention strategy.

HIV prevention can also be accomplished by interventions at the *medical/technological level*, by technological means through health care (such as virucides and microbicides). Routine treatment of donated blood, treatment of sexually transmitted diseases, treatment for drug and alcohol abuse, programs for the mentally ill (associated with HIV risk among homeless populations), and antenatal care have all been shown to be effective strategies for reducing HIV transmission.

Putting It All Together

Australia and New Zealand implemented sound HIV prevention practices and policies at all levels early in the epidemic, and the spread of new infections has been largely contained. The Australian and New Zealand responses to the epidemic retarded the spread of HIV among injecting drug users (IDUs) and heterosexuals, and decreased the spread of new infection transmitted through homosexual contact. Australia reported 5,833 cases of AIDS (72 percent, or 4,196 individuals, deceased) to the end of March 1995, and New Zealand reported 501 cases of AIDS (80 percent, or 403, deceased) to the end of June 1995 (National Centre in HIV Epidemiology and Clinical Research, 1995). The major mode of transmission in both countries has and continues to be homosexual transmission (about 80 percent of cases and new infections). In New Zealand, HIV infections among homosexually active men peaked in the mid-1980s. In Australia, the number of newly diagnosed infections occurring in homosexually active men decreased from a peak of 2,284 in 1987 to 772 in 1994. A marked decline in unsafe sexual practices among homosexually active men has also been documented (Crawford et al., 1995). In both Australia and New Zealand, the potential epidemic among IDUs has been halted, and there has been no increase in HIV and AIDS in the past 5 years or so among this risk group (National Centre, 1995).

Expanding the Definition of Prevention Science

This discussion of effective approaches for reducing or modifying behaviors likely to transmit HIV obviously expands intervention strategies beyond those used traditionally in clinical, epidemiological, or social and behavioral sciences. HIV prevention must incorporate new understandings of "prevention science." Cates (1995) defined prevention science to include both qualitative and quantitative analytic approaches and a variety of disciplines to address multiple levels of the causes of the spread of HIV: anthropology, sociology, psychology, political science, communication sciences, epidemiology, economics, statistics, managerial science, clinical medicine, and laboratory science. Prevention science is defined as "a collection of diverse fields that, when used together, creates a whole of prevention knowledge greater than the sum of its component parts." Obviously, a wide variety of research designs must be used for the preventions sciences.

Future Directions

The challenges of HIV prevention have and continue to be enormous. HIV prevention research needs to develop and test interventions especially at the dyadic/family and community level. Research must also be initiated at the levels that are more difficult to study and less easily framed within an NIH framework, such as the policy/legal and superstructural levels. The research design should be formulated to answer the question; the research design should never determine the kinds of questions that are asked. Clearly taking the cue from other preventable diseases and health problems, interventions that address social and legal systems within which individuals live and make choices have extremely profound effects on the public health. Using such strategies will be essential in the fight against HIV.

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Some Principles for Preventing HIV: Rigor or Reality in Study Design

Mervyn Susser, M.B., B.Ch., F.R.C.P.(E.), D.P.H.

Introduction

Research design is a means of eliciting, as best we can, the valid relations between cause and effect. The definitive properties of causes are only three. Arranged in ascending order of decisiveness, they are:

- Association between putative cause and putative effect.
- Time order between putative cause and effect.
- Direction from putative cause to effect.

HIV preventive interventions are intended to be causes in the broad sense—in this instance, causes that limit disease or block its emergence. Hence, the criteria we need to judge the effects of the interventions we design are readily at hand in the criteria we use to judge that the properties of causes are present.

Conclusions

A key, if mundane, conclusion is that in order to select and devise effective designs, they need to be matched to clearly defined questions. The questions themselves need to be understood in all their dimensions and levels.

Choice of Interventions

In the choice of interventions in the HIV epidemic, two desirable elements of design, rigor and applicability—or internal and external validity, as they are sometimes referred to—are problematic. In a given study, they are always in conflict. Thus, choices involve necessary trading between the degree of rigor, which is the ability to distinguish both the determinant and the outcome from other related factors, and the degree of applicability, which is the ability to make legitimate extrapolations of observed relations beyond the circumscribed study conditions.

Rigor thus derives from the confidence one can place in the presence of the true and definitive properties of the putative causes elicited.

This confidence resides in large part in two other elements of design:

- The degree of change in the determinant—here the intervention—mobilized by the design.
- The degree of isolation of the determinant and outcome from other factors (covariates, etc.).

A hierarchy of design classified by rigor is as follows:

- Controlled experiment.
- Quasi-experiment.

- Observation of sequential events (which appears in two main forms): (a) longitudinal, (b) case-control.
- Cross-sectional survey.

Applicability: Individuals and Context

Study designs in the population sciences, including epidemiology, are nearly always for populations of individuals disjoined; that is, the study takes no account of the dynamics of the social entities and contexts in which individuals live and work. To step beyond this individual level of organization, we need an ecological epidemiology (eco-epidemiology). In essence, the ecological approach designates groups as the units of study. The essence lies in recognizing and dealing with different levels of organization.

To conceptualize distinctive effects of groups on the individuals within them, at least three variables peculiar to groups must be denoted:

- Integral variables (sometimes called structural variables).
- Contextual variables (sometimes called derived variables).
- Dependent happenings or contagion (in HIV prevention, these correlated dependent variables are especially important to recognize).

Choosing Appropriate Designs

Keeping in mind the background of possible designs and the necessity of accounting for context, we can match designs to particular questions at issue.

First, we pay our respects to the randomized controlled trial (RCT) for its unexcelled rigor. When should RCTs be used at individual and group levels in HIV prevention, or should they be used at all?

- At the individual level, the RCT is, when feasible, the best vehicle for direct tests of narrow hypotheses regarding vaccines, treatments, and measurable individual behavior change.
- At the community level, however, the RCT can be the best vehicle for intervention only under special conditions. The conditions are a sufficiency of communities for statistical power, a simple measurable intervention (e.g., a vaccine or training in cognitive skills), and a simple measurable outcome (e.g., infected versus uninfected subjects or a change in a clearly demarcated situation or behavior). Not least, variation between communities at the individual level needs to be reckoned with, especially when the number of community units is small.
- Again, at the community level, the RCT will seldom be a suitable vehicle for a complex community intervention, especially those of long duration, such as efforts to change social norms (values, expected behavior, and actual behavior).

In community-level interventions, two particular factors are often not susceptible to control and create difficulties. The first is contamination of the control group by the intervention directed at the experimental group. The second resides in time-lags between intervention and effect in the mobilization of social process.

In regard to complex interventions in the HIV epidemic, efforts to control tobacco addiction provide an analogy, a model, and a cautionary tale. In the matter of achieving and demonstrating control, reality largely neutralized the rigor of even the best community-level interventions. Nonetheless, large and dramatic social changes in both smoking norms and smoking behavior took place. Why then did the community trials fail to show noteworthy effects? Ironically, they were the victims of the much-delayed success of a sustained social movement against smoking. However, such success emerged only after two decades of research and action. Reality intruded in the form both of contamination and of time-lag between intervention and effect. In essence, the control communities were thoroughly contaminated by many elements of the intended experimental intervention that had long pervaded society.

Future Directions

The following are some recommendations for preventing HIV transmission and measuring the effects of prevention interventions:

- Take another leaf out of the smoking story: set about building a social movement in a conscious and purposeful way.
- Build a sensitive surveillance system for monitoring the diffusion of new norms of behavior, not just outcomes in terms of disease transmission. In the United States much is in place.
- Use designs appropriate to the purpose, and pay particular attention to the appropriate level of organization.
- Finally, when all these things are in place and going strong, have patience. As noted, it took 10–20 years, depending on how one counts, even to begin to see the definitive signs of the cultural revolution against smoking. Pay the price one must pay for freedom, which is eternal vigilance.

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Theoretical Models of HIV Prevention

Martin Fishbein, Ph.D.

Introduction

Despite the best efforts of biomedical researchers, there is in the second decade of the AIDS epidemic still neither a cure for nor a vaccine to prevent this deadly disease. Yet HIV infection is preventable, primarily through behavior change. Efforts to prevent AIDS must rely on an understanding of the factors that influence behavior and behavior change.

Conclusions

Targeted, theory-based interventions can change behavior. There are only a limited number of theoretical variables (or psychosocial determinants) that need to be considered in attempts to predict, understand, and change behavior. The impact of a given behavior change on the AIDS epidemic will depend on local circumstances, such as prevalence of the disease and sexual mixing patterns in the population.

Role of Behavior in Transmission of HIV

To best understand the role of behavior change in preventing the further spread of HIV, it is helpful to examine the May & Anderson (1987) model of the reproductive rate of a sexually transmitted disease:

$$R_0 = c\beta D,$$

where R_0 = reproductive rate (of transmission), β = measure of infectivity or transmissibility, c = measure of interaction rates between susceptibles and infectors, and D = measure of duration of infectiousness.

Because each of the elements in the right side of the equation can be influenced by behavior change, the model suggests that there are many behaviors that affect the rate of HIV transmission. For example, the degree of infectivity or transmissibility (β) can be decreased by increasing condom use or by delaying the onset of sexual activity. The interaction rate (c) can be influenced by decreasing the rate of new partner acquisition or increasing monogamy. Although there is no way at present to change the duration of infectiousness (D) for HIV, it should be noted that sexually transmitted diseases (STDs) serve as co-factors in HIV transmission (i.e., they influence β) and duration of infectiousness (D) is a very important parameter in reducing the transmission of STDs. Thus, if one can increase the likelihood that people will participate in screening or if they can be motivated to seek early treatment for symptomatic STDs, this will reduce the duration of infectiousness (D) for an STD, which ultimately reduces seroincidence.

If an effective behavioral intervention (e.g., one leading to a 15 percent increase in condom use) is introduced in a population that has low HIV prevalence, there may be little or no impact on disease. However, such an intervention could lower the probability of an epidemic if HIV were introduced into that low-prevalence population; persons would already have been inoculated (behaviorally) against the threat of HIV if at some point HIV were introduced into the social system. Yet this same intervention could have a dramatic impact on HIV seroincidence if it were introduced in a population with high seroprevalence.

Clearly, the impact of any given behavior change (like the impact of any STD control program) will depend on many factors, not the least of which is the prevalence rate of the disease in the population under consideration. Although it is possible to model the effects of a given increase in condom use (or decrease in STDs) on the HIV epidemic, it is important to recognize that the same 10 or 15 percent increase in condom use (or reduction in STD rates) will have very different impacts on the transmission of HIV (or any other STD), depending on local prevalence rates and/or the sexual mixing patterns in the population. For this reason, more than any other, it is imperative to evaluate the effectiveness of behavior change interventions by considering the extent to which they change behavior, not merely their impact on the transmission of HIV or other STDs. In addition, although considerably more research is necessary to enable a fuller understanding of the interrelations among behavior change, STD rates, and HIV incidence, a number of models can help determine the impact of a given behavior change in a given population.

To produce change in a given behavior, however, it is important to first understand the factors underlying the performance (or nonperformance) of that behavior. A better understanding of why people behave the way they do will most likely lead to development of more effective interventions to change behavior. Although, at a substantive level, it can be argued that every behavior has its own unique set of determinants, there is a growing consensus that, at the theoretical level, only a limited number of variables need to be considered in order to predict and understand any given behavior.

To illustrate this point, the three theories that have had the greatest impact on AIDS intervention research—the Health Belief Model (Rosenstock, Strecher, & Becker, 1994), the Social Cognitive Theory (Bandura, 1994), and the Theory of Reasoned Action (Fishbein, Middlestadt, & Hitchcock, 1991)—will be briefly reviewed. These theories represent a public health, a clinical, and a social-psychological approach to understanding behavior and behavior change. Although there are no real competitors to the Health Belief Model (Rosenstock, Strecher, & Becker, 1994) within the public health domain, there are other clinical and social psychological theories of behavior, and two of these—the Theory of Self-Regulation and Self-Control and the Theory of Interpersonal Relations and Subjective Culture—will also be briefly reviewed. The results of a workshop, which brought together the developers of these five theories to discuss the similarities and differences among their theories, will be described in this presentation (Fishbein et al., 1992).

Although this group of theorists could not agree on a “consensus model,” they agreed on the variables that are central to predicting and understanding a given behavior:

- The intention to perform (or not perform) the behavior

Example: “I will use a condom every time I have sexual intercourse.”

- The skills and abilities necessary for behavioral performance

Example: Respondent knows how to and is capable of sterilizing needles and other injection equipment.

- The presence or absence of environmental constraints that could prevent behavioral performance

Example: Condoms are not available (i.e., cannot be purchased).

- The attitude toward performing the behavior, which is based on outcome expectancies (or beliefs that performing the behavior will lead to certain positively or negatively valued outcomes)

Example: “My using a condom every time I have sexual intercourse is a good thing to do.”

- Perceived norms concerning behavioral performance

Example: “Most people who are important to me think I should always use sterile injection equipment.”

- Self-standards with respect to performing the behavior

Example: “I am the kind of person who always uses a condom when I have sexual intercourse.”

- Emotional reactions vis-a-vis the behavior

Example: “When I think about asking my partner to always use a condom, I get anxious and upset.”

- Self-efficacy with respect to behavioral performance

Example: “Although lots of things can get in the way (e.g., my partner being high, my feeling lonely) of using condoms, I can use a condom every time I have sexual intercourse.”

There was also consensus in the workshop that the first three variables are probably necessary and sufficient to predict a given behavior. That is, the probability that a given behavior will be performed is very close to 1.0, if the following three conditions have been met: (1) the person has formed a strong intention (or made a commitment) to perform the behavior, (2) he or she has the skills and abilities required for behavioral performance, and (3) there are no environmental constraints to prevent behavioral performance.

One implication for developing behavioral interventions is that very different types of interventions will be necessary depending on which of these variables reduces the likelihood that a given behavior will be performed. For example, interventions required if one has not already formed a strong intention to perform a behavior are different from interventions required if one has formed the intention but either does not have the necessary skills and abilities to carry it out, or if one finds that environmental constraints are preventing one from acting on that intention. If the problem is motivational—that is, if a strong intention has not yet been formed—the intervention should address one or more of the remaining five variables.

The relative importance of these variables as determinants of intention (and behavior) depends on both the behavior and the population under consideration. Thus, for example, one intention may be primarily controlled by attitudinal considerations whereas another may be most strongly influenced by normative considerations. Similarly, whereas a given behavior may be primarily under attitudinal control in one population, it may be under normative control or most strongly influenced by self-efficacy in another. Thus, it is important to empirically identify those factors that most strongly influence a given behavior in a given population and then use this information to design interventions.

Other points of consensus will also be discussed along with several other implications of behavioral theory for the development, implementation, and evaluation of behavior change interventions.

Future Directions

Research is needed to understand the interrelations among behavior changes, STD rates, and HIV incidence. Both theory-based behavioral interventions and STD control programs can have an impact on HIV transmission. Research is needed to understand the relative effectiveness of these two approaches, as well as the relative efficacy of a combined behavior change/STD control program and

drug treatment and HIV incidence. Some of the variables identified by the theorists (e.g., self-standards, emotional reactions) have not been fully investigated or subjected to empirical tests. Research evaluating the importance of these variables as determinants of behavior and as factors influencing behavior change is necessary.

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Consequences of HIV Prevention Interventions and Programs: Spectrum, Selection, and Quality of Outcome Measures

David R. Holtgrave, Ph.D.

Introduction

A spectrum of sound outcome measures from self-reported behavior change to HIV seroincidence is essential in evaluating HIV prevention programs and interventions (Coyle et al., 1991). Self-reported changes in behavior can have solid psychometric properties (valid and reliable) if rigorous methodologies are employed. Linkages between self-reported HIV-related risk behaviors and HIV transmission can be made using complex mathematical modeling methods.

Conclusions

Three major points will be made in this presentation:

- The consequences of HIV prevention interventions and programs can be measured in a wide variety of ways; the choice of outcome measures should be driven by the type of evidence that is required to answer the research questions and determine the efficacy of AIDS prevention programs. The information needs of public health decisionmakers who have the ultimate responsibility for managing and allocating resources among effective AIDS interventions and programs must also be considered.
- Self-reports of sex and drug use behaviors can be reliable and valid outcome measures if rigorous assessment strategies are employed.
- Some sex and drug use behaviors are empirically associated with a higher probability of HIV transmission, and this can be modeled in different populations.

Range of Outcome Measures in Research

The selection of appropriate outcome measures in studies of the efficacy of HIV prevention interventions depends on a range of issues: (1) availability of behavioral assessments with good psychometric properties that are also culture and gender appropriate; (2) whether sufficient members of at-risk population can be recruited and maintained in a longitudinal study; (3) access to laboratory facilities to conduct STD or HIV tests; and (4) research dollars available.

Most research studies on the efficacy of HIV prevention interventions have focused on self-reported behavioral outcomes; a small number have utilized STD and HIV infection as outcome measures. Examples of studies using each of these general types of outcome measures will be presented through this conference. As will be seen in this presentation, the behavioral outcome measures have included the following: (1) condom use measured on a per-act basis; (2) condom use measured on a per-partner basis; (3) number of sex partners; (4) number of risky partners; (5) frequency of particular sexual behaviors (such as vaginal intercourse); (6) condom redemption coupons; (7) number of partners with whom drug injection needles and syringes are shared; and (8) frequency of particular drug injecting behaviors. This presentation will review the psychometric

A National Research Council panel found that the test/retest reliability of self-reports of sexual risk behaviors is generally good, especially over short recall periods (Miller, Turner, & Moses, 1990). Several approaches have been used to assess the validity of self-reports of sexual risk behaviors. For instance, the same National Research Council panel found that the concordance between partners' independent reports of physical aspects of sexual behaviors tended to be good. Other validation approaches (such as urinalysis in the case of drug use and confronting respondents with the prospect of being subjected to a lie detector test) have provided additional evidence of the validity of self-reported behaviors.

Needle and colleagues (1995) examined the test/retest reliability of self-reports of drug use behaviors and found it to be high. The National Research Council panel referred to above stated that urinalysis could be used to assess the validity of self-reports of drug use behaviors. The overall data suggest that self-reports of such behaviors tend to be valid; however, the data vary depending on the assessment method used, and there is some tendency toward underreporting drug use. Important lessons have been learned that can help researchers assess self-reports of sex and drug use risk behaviors in reliable and valid ways.

Linkages Between Behavioral Outcomes and HIV Infection

Because a major purpose of HIV prevention interventions and programs is to reduce transmission of the virus, HIV seroconversion data are important. A small number of large-scale studies have used HIV seroconversion as an outcome measure. However, such biological measures have important limitations that must be considered, even though tests for HIV antibodies are quite sensitive and specific. First, asking respondents to submit to repeated blood draws during the course of a study could introduce bias and limit the generalizability of the study results. Second, because HIV seroconversion is a relatively infrequent event, the sample size for a study using HIV infection as an outcome measure may need to be very large. Third, the relationship between sex (or drug use) risk behaviors and HIV infection is not a simple linear relationship. Rather, it is complex and nonlinear and depends on a number of contextual factors, as will be discussed below. Hence, HIV seroconversion is a feasible outcome measure only under certain circumstances.

Even when data on HIV infections are not available, epidemiological models may be used to link behavioral outcome measures to estimates of HIV infections prevented by the intervention. (Holtgrave and Kelly [1996] recently employed this technique in a cost-effectiveness study of an HIV prevention intervention for women at risk of infection.) These models have an empirical basis that rests primarily on long-term epidemiological cohort studies, which track both behavioral and biological measures, and on studies of HIV-serodiscordant couples that monitor behavioral measures and HIV serostatus of the initially uninfected partner (Brookmeyer & Gail, 1994).

These models are essentially epidemiological equations that describe HIV transmission. For example, according to a Bernoullian model of HIV transmission, the overall risk of infection for a person having n sexual contacts with m different partners is as follows:

$$1 - \{p[1 - r(1 - fe)]_+ + (1 - p)\}^m,$$

where p is the HIV prevalence among sex partners, r is the risk of HIV infection of one act of unprotected sex, f is the fraction of sex acts in which condoms are used, and e is the effectiveness of condoms in blocking transmission of HIV. This equation can be easily generalized to account for multiple risk behaviors, including various sexual and drug use behaviors. Brookmeyer and Gail (1994) provide an overview of Bernoullian and other types of epidemiological models that link sex and drug use risk behaviors to HIV infection. There are many empirical demonstrations of increases in risk

behaviors leading to increases in HIV transmission. One important qualitative finding is that HIV infection is related closely to the number of a person's sexual partners.

Future Directions

As new strategies for alternative means of HIV testing (e.g., oral fluid tests) become available, their feasibility for use in HIV prevention trials should be evaluated further. These alternative testing methodologies have some potential for making biological HIV outcome measures more feasible.

However, even if biological measures become more widespread, behavioral measures should not be abandoned. Indeed, behaviors are the modes of HIV transmission, and prevention interventions work by modifying HIV-related risk behaviors. Therefore, further empirical efforts should refine the existing specifications of the functional relationships between HIV-related risk behaviors and biological outcome measures.

Progress should be made toward identifying a minimum data set of behavioral variables to be measured in all behavioral intervention trials. This would facilitate comparisons of results across studies, and better enable mathematical modeling analyses linking behavioral outcomes to estimates of HIV infections prevented by interventions.

Efforts should be made to study program managers' and policymakers' uses of various outcome measures in their decisionmaking about HIV prevention programs. Their information needs should be considered in outcome measure selection. The extent to which currently used outcome measures actually provide them the requisite information should be formally assessed.

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Behavioral Interventions with Gay and Bisexual Men and Youth

Jeffrey A. Kelly, Ph.D.

Introduction

Throughout the decade after the first AIDS cases were identified, the HIV disease epidemic in the United States and in many developed countries throughout the world was largely driven by infections that had been contracted in the 1970s to mid-1980s by predominantly white gay and bisexual men in major AIDS epicenters such as New York, San Francisco, Los Angeles, and other large cities. Of all adult AIDS cases reported in the United States through June 1995, 52 percent have been among men who have sex with men (MSM) and who report same-sex contact as their only exposure to risk.

Conclusions

Studies described below illustrate that behavioral intervention, whether delivered in face-to-face group or workshop programs or in the context of community-level interventions, can assist gay men in making behavior changes to reduce their risk for HIV infection. Risk-reduction skills training and assistance in planning how to implement change in personal relationships appear to be a primary component underlying the success of face-to-face interventions; the promotion of social norm changes to encourage risk avoidance appears to be a major component contributing to the effectiveness of community-level interventions. Both levels or strategies of intervention can contribute to the success of HIV prevention efforts among MSM, especially when adapted to meet the needs of the segments of the gay population who remain vulnerable to HIV/AIDS.

Effectiveness of Face-to-Face Interventions To Reduce HIV Risk Behavior

A number of studies have evaluated the impact of intensive small-group or workshop interventions to assist gay men in enacting sexual behavior changes to reduce risk for HIV infection. The most definitive of these studies has employed randomized clinical trial (RCT) designs and has evaluated the effectiveness of intervention on sexual risk behavior, with risk behavior change self-reports corroborated by change in other validation measures. The procedures and outcomes shown in three of these randomized intervention outcome studies will be considered here.

Kelly and colleagues (1992) recruited a sample of 104 men from the community, all of whom reported high-risk sexual practices with male partners in the past year. Following individual assessment of each participant using a battery including measures of sexual behavior in the past 4 months, sexual behavior self-monitoring, AIDS risk behavior knowledge, and role play enactments to assess behavioral skills for resisting coercions to have risky sex, men were randomly assigned to either a 12-session, small group, HIV risk reduction intervention, or waiting list control group. The 12 weekly sessions, derived from cognitive-behavioral behavior change principles, focused on (1) AIDS risk education; (2) skills training exercises in condom use, sexual assertiveness, and initiating discussions of safer sex; (3) self-management training to help participants identify personal “triggers” to risky sex and alternative ways to handle those triggers; and (4) exercises to teach risk-reduction, cognitive self-guidance, and self-reinforcement skills, emphasizing the linkage of risk reduction to themes of pride, self-respect, and responsibilities to protect oneself and others. All participants were followed for 8 months and readministered the same assessment battery completed at baseline. Among participants who received the intervention, condom use measured by both retrospective and diary measures increased from 20 percent to over 70 percent of all intercourse occasions, and rates of unprotected anal intercourse decreased from a mean of 8.0 occurrences per 4-month period at baseline to an average of 0.5 occurrences in 4 months following intervention. Behavior change was corroborated by improvement in AIDS risk knowledge

and objectively assessed role-play sexual assertiveness skills from baseline to followup. No corresponding change was found among control group participants until they were later offered the same intervention for ethical reasons.

In a different intervention format, Valdiserri and coworkers (1989) evaluated the effectiveness of extended single-session workshop risk reduction interventions for gay and bisexual men. In this study, a sample of 292 men were randomly assigned to either a workshop that emphasized AIDS risk education or a workshop that included not only risk education but also extensive risk reduction skills training practice and exercises to promote the adoption of safer sex changes. Prior to participation in one of the two workshops, each man completed measures assessing risk knowledge, attitudes, change intentions, and sexual behavior practices. Participants were followed for 12 months after completing their workshop and were readministered the same measures. Although all participants showed evidence of improved knowledge and practical understanding about risk reduction, those who participated in the enhanced skills-based intervention exhibited greater change in risk-reduction attributes, intentions, and sexual behavior practices, including higher levels of condom use at 6- and 12-month followup. For these enhanced-intervention participants, the proportion of men consistently using condoms increased from 36 percent in the 6 months before baseline to 80 percent at 1-year followup.

The two intervention trials just described enrolled both white and ethnic minority MSM, but the samples predominantly comprised white men. A recent HIV prevention intervention outcome study reported by Peterson and colleagues (1996) recruited a cohort of 318 African American MSM. This sample is important because of the disproportionately high HIV infection rates among minority MSM. Following baseline risk assessment, participants in the Peterson et al. (1996) study were randomly assigned to a 3-hour intervention, a 9-hour intervention, or a control condition. The intervention elements were very similar to those used in the studies previously described and included risk education, cognitive and behavioral risk-reduction skills and self-management training, and safer sex negotiation skills practice, as well as including a focus on positive self-identity. When participants were followed for 18 months postintervention, little evidence of sexual risk behavior change was found among men in the control group, with only modest change among the brief intervention participants. However, men who had attended the 9-hour intervention—delivered in three 3-hour workshops—reduced their risk behavior. The proportion of men reporting any unprotected anal intercourse in the past 6 months declined from 45 percent at baseline to 20 percent at 18-month followup. Thus, interventions focused on cognitive-behavioral skills of considerable intensity or dosage have proven effective with ethnic minority MSM.

These studies show, using RCT designs, that it is possible to assist gay and bisexual men to make behavior change to lessen their risk for contracting HIV infection. A common element underlying these successful trials is the focus on extending beyond AIDS education alone, teaching participants critical risk-reduction skills and providing assistance in helping participants in planning how to apply those skills in personally relevant relationships and situations.

Effectiveness of Population-Focused, Community-level Risk Reduction Interventions

A different level of intervention is that which seeks to change population risk behavior through community (rather than individual or small group) programs. Because perceived peer or social reference group norms concerning safer sex have been closely associated with individuals' levels of risk behavior, community-level interventions have particularly sought to modify social norms so as to encourage risk reduction and discourage high-risk behavior. In the past several years, there have been several promising results of controlled community-level risk reduction intervention field trials.

Kelly and colleagues (1992) reported on the outcomes of an intervention, delivered sequentially in a lagged or multiple baseline design, to populations of men patronizing gay bars in three southern cities. To establish baseline levels of risk, anonymous surveys were administered to all men entering all gay

bars in each city. These data revealed that an average of 37 percent of men in the populations reported engaging in unprotected anal intercourse in the past 2 months. The intervention tested in this study was based on “diffusion of innovation” theory, which postulates that behavior change in a population can be induced when a sufficient number of key and popular opinion leaders of the population exhibit, visibly endorse, and model new behavior, thereby producing both norms and behavior changes that diffuse throughout the population. At the time in this study when intervention was to be sequentially introduced in each city, bartenders in each club were taught to identify the 15 percent of club patrons who were observed to be most popular with male peers. The cadres of popular opinion leaders were then recruited to attend a series of four group sessions that provided training in how to communicate AIDS prevention endorsement messages to their friends and engaged the opinion leaders to initiate and maintain these conversational messages.

Effects of the intervention were assessed by repeating surveys of all men entering a city’s bars at 3-month intervals following intervention in that city and comparing population risk levels found following intervention with those found at baseline in the city. In each community, reductions were found in the proportion of population members who reported engaging in any unprotected anal intercourse; reductions of 15–29 percent in the proportion of population members reporting risky sex were found in the cities. In addition, the survey data revealed that population norm perceptions concerning the social acceptability of insisting on safer sex shifted following intervention, indicating that the intervention produced both social norm and population risk behavior changes.

Utilizing a similar design, Kegeles, Hays, and Coates (1996) recently described results of community risk-reduction intervention focused on young gay men in two west coast cities. In this project, key opinion leaders were again identified in each city’s population of young gay men, and these key leaders delivered HIV prevention endorsement messages to their friends. In addition, risk reduction workshops, social events that included AIDS prevention messages, and print and graphics AIDS education materials were disseminated in venues frequented by young gay men in each city. The intervention was evaluated by means of risk behavior surveys administered to longitudinally followed cohorts of young gay men in the cities. Relative to city populations that had not yet received the community-level intervention, reductions in population risk behavior were observed at 1-year followup in communities that had received intervention. Within the intervention city cohort of young gay men, the proportion of men engaging in any unprotected anal intercourse in the past 2 months decreased from 41 percent to 30 percent, about a 27-percent reduction from baseline and similar to the magnitude of change reported by Kelly and coworkers.

Future Directions

Although the proportion of new HIV infections accounted for by MSM has declined over the past several years, largely due to a leveling in the rate of HIV incidence among gay men in the urban epicenters that originally drove the American epidemic, HIV prevention efforts focused on gay and bisexual men remain urgently needed for several reasons:

- Between 1994 and 1995, and based on data from states with confidential reporting, 35 percent of new HIV infections among men reported to the Centers for Disease Control and Prevention were attributable to male same-sex behavior as the sole exposure category.
- The risk behavior changes and stable incidence of new HIV infections among largely white, older, and well-educated urban gay men stand in contrast to still-increasing HIV incidence and high levels of risk behavior documented among young MSM and, especially, racial minority young gay or bisexual men. HIV incidence in this population segment is 3 percent per year in many areas, and the general observation that new HIV infections are increasingly associated with youth and minority status are true among MSM as well as other groups.

- There is a trend of increasing rates of new infections among MSM living in geographical areas outside the traditional and original AIDS epicenters.

- Because HIV is now extremely prevalent among gay men in many large cities, it requires progressively “less” risk behavior to confer threat of contracting infection. In cities such as San Francisco and New York, where HIV infection prevalence among MSM is 35–45 percent, nonmonogamous gay men are likely to quickly encounter infected partners, and unprotected anal intercourse with those partners creates opportunities for efficient HIV transmission. Inconsistent maintenance of behavior change (“relapse”)—a phenomenon well documented in the behavioral epidemiology literature among MSM even in cities with longstanding AIDS prevention efforts—carries great threat and requires a focus on behavior change maintenance.

Taken together, these patterns indicate that HIV prevention interventions are particularly needed for young and ethnic minority men who have sex with men; that MSM who live in what have been considered AIDS “second-tier” areas remain a vulnerable population; and that the high prevalence of HIV among urban gay men, coupled with evidence of frequent lapses to unsafe sex, requires increased attention to change maintenance and relapse prevention interventions.

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Interventions To Reduce Heterosexual Transmission of HIV

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Introduction

Based on World Health Organization (WHO) estimates, approximately 6,000 persons are infected with HIV each day (WHO's Primer on AIDS, 1996). For 70–80 percent of those persons, the mode of transmission is heterosexual intercourse (Mayer & Anderson, 1995). In the United States, heterosexual transmission of HIV infection is the fastest growing mode of infection (Centers for Disease Control and Prevention [CDC], 1996). The increase in the number of heterosexual transmissions is due to several factors, including sexual activity among injecting drug users (IDUs), substance use (e.g., methamphetamine) that increases sexual transmission risk (Rotheram et al., 1994), sex with multiple partners, sexual practices that involve bleeding or acts that increase risk (e.g., anal sex), cervical ectopy, and being uncircumcised (Mayer & Anderson, 1995).

This review will focus on HIV interventions aimed at reducing sexual risk acts conducted with heterosexuals in four areas: (1) individuals at high risk (i.e., those with sexually transmitted diseases [STDs], the severely mentally ill, IDUs, and pregnant HIV-positive women); (2) interventions with couples; (3) community-level interventions; and (4) national programs. The review will not be limited to randomized controlled trials; in several areas natural experiments have provided important information demonstrating the impact of HIV interventions.

Conclusions

The absolute increases in condom use have consistently been in the range of 20–30 percent in response to small-group HIV interventions for heterosexuals at high risk. The impact of the programs varies based on the number of sessions and their length (i.e., the dose of the intervention, the targeted outcome [increased condom use, reductions in the numbers of sexual partners]), the target population (IDUs, persons with an STD), and the context of the intervention (individuals, couples, communities, nations). The most intensive programs have been delivered to those at moderate risk of transmitting to others (the severely mentally ill, those with STDs, and those living in high-risk settings). Few prevention programs have been developed for seropositive persons and serodiscordant couples, those at highest risk of transmission. When interventions attempt to change both injecting drug use and sexual risk, the interventions appear to be less effective. Only a few programs have been tailored for heterosexual men.

Interventions Aimed at Individuals

Overall, there are 26 published studies of HIV prevention programs with persons at high risk for HIV; 22 demonstrate positive changes in HIV risk acts. The targeted outcomes, dose, and durations of the followups vary substantially. Based on social cognitive theories, the intervention programs have attempted to change self-efficacy, peer and partner norms, outcome expectancies, problem solving and negotiation skills, and knowledge of HIV. Typically, small groups of 8–10 persons are assembled for multiple sessions with a trained facilitator. The participants are randomly assigned to an intervention or a control condition and evaluated prior to the intervention, immediately following, and several months later.

Persons With Sexually Transmitted Diseases

Seroprevalence rates in STD clinics range from 0.1 to 11 percent (Weinstock et al., 1995). Six of eight studies delivered a one-session intervention. In contrast to the findings with other populations, one-session interventions in STD clinics show reductions in rates of STDs over 6 months (e.g., Cohen et al., 1991, 1992). Five reported reductions in HIV risk acts; three found reductions in the rates of STDs. The impact of the interventions varied among persons of different ethnicities (Weinstock et al., 1995). One study found improvements in both intervention and control conditions, raising the question of the potential short-term positive impact of conducting risk assessments (O'Leary et al., in press).

The largest and most tightly controlled of these investigations is Project Respect, a multisite randomized controlled trial that evaluated the relative efficacy of three interventions over 12 months and maintained a 65-percent followup rate (Kamb et al., 1996). HIV-negative participants (n = 5,872) were randomly assigned to receive one of the following: (1) two HIV education sessions; (2) two sessions aimed at increasing risk perception and condom use; or (3) four sessions of enhanced, skill-focused sessions. At 3 months, having ever used a condom and always using a condom increased with both main and casual partners by about 20 percent; 8 percent decreased their condom use.

Persons With Severe Mental Illness

Seroprevalence rates have ranged from 4 percent to 23 percent among those with severe mental illness (Carey, Weinhardt, & Carey, 1995; Cournos et al. 1994). Two successful programs have been conducted delivering small group interventions over multiple sessions. A four-session intervention resulted in significant increases in AIDS knowledge and intentions to use condoms at a 1-month followup among severely mentally ill persons (Kalichman et al., 1994, 1995). Susser et al. (1993) intervened with 97 homeless mentally ill men in New York City over 15 sessions and found increases in condom use and reductions in risk behaviors over 6 months.

Injecting Drug Users

Sex partners of IDUs are at risk for HIV transmission due to the high seroprevalence among IDUs. Twelve studies with IDUs have included sexual behavior in the intervention program (Gibson et al., 1989). These programs are significantly less successful than those targeted only at changing sexual risk acts. Seven of these studies have been of one session's duration. Ten have evaluated changes in sexual risk acts; seven studies demonstrated no changes in sexual risk acts. Baker et al. (1993) provided a six-session intervention aimed at changing needle-sharing behavior and sexual risk acts. While significant changes were found in needle-cleaning and -sharing acts, there were no significant changes in sexual risk acts. Three studies demonstrated positive behavioral changes in sexual risk acts.

Persons With High Rates of Risk Acts

At least five intervention studies have been conducted among low-income, inner-city populations. The programs ranged in duration from one session (one study) to 6 months (1 study); two studies lasted 6–8 sessions. Four of these studies found reductions in HIV-related risk acts. There have been two studies of college students at high risk; both programs focused on enhancing relational skills. A one-session of HIV testing was compared with an AIDS education session (Wenger, Linn, Epstein, & Shapiro, 1991). Both interventions reduced the numbers of sexual partners, but self-reports of condom use were significantly higher among those who received the AIDS education session (Wenger et al., 1991).

Prevention of Vertical Transmission

Couples with an HIV-positive partner must decide whether to have children and, if the woman is pregnant, whether to be tested for HIV and take medications during pregnancy. The results of the

ACTG 076 trial suggest that zidovudine (AZT) during pregnancy will reduce vertical transmission threefold. Although currently no interventions have included randomized controlled trials of reproductive counseling including serotesting and use of AZT, the rates of undetected infections among pregnant women can be examined. For example, in North Carolina, 60 percent of seropositive mothers were identified as seropositive during pregnancy; this figure rose to 82 percent in 1994 and 90 percent in 1995. In contrast, among the collaborators on the initial ACTG 076, fewer than 50 percent of seropositive mothers were identified during pregnancy. Of those who knew they were HIV positive, 75 percent chose to follow the AZT protocol. When seropositive women in Rwanda received an intervention including birth control, the number of women getting pregnant dropped from 22 percent to 9 percent (King et al., 1995).

Interventions To Reduce Transmission Among Couples

Although not randomized control interventions, two critical investigations demonstrated that increases in condom use among serodiscordant couples (i.e., one seropositive and the other not) are associated with reductions in seroconversions within a 1-year period. The European Collaborative Study examined 304 serodiscordant couples over 20 months (de Vincenzi, 1994). Every 6 months the serodiscordant couples were counseled and the seronegative person was tested for HIV. Almost half of the couples (48.4 percent) used condoms consistently. There were no seroconversions among those who used condoms consistently; however 9.9 percent seroconverted (4.8/100 person years) among those who did not consistently use condoms. Condom use was directly linked to fewer seroconversions. A similar pattern was demonstrated among 144 serodiscordant couples in San Francisco (Padian et al., 1993). Followed for a median of 1.5 years, there were no seroconversions among couples who used condoms consistently. Together, these studies support the use of increased condom use as an effective outcome of an HIV prevention program.

Community Intervention Methods

Three successful HIV intervention programs have been delivered to all persons within a specific geographic area. The AIDS Community Demonstration Projects (ACDPs) were community-level HIV intervention programs targeting high-risk, hard-to-reach populations in five U.S. cities: Dallas, TX; Denver, CO; Long Beach, CA; New York, NY; and Seattle, WA (CDC, 1996). Interventions were developed for IDUs recruited off the streets, female sex partners of male IDUs, women who trade sex for money or drugs, men who have sex with men but who do not identify as homosexual, street youths, and residents of areas with high rates of STDs and injection drug use. Based on social cognitive theories of health beliefs (Becker, 1974), reasoned action (Fishbein & Ajzen, 1975), self-efficacy (Bandura, 1986), and the stages of change model (Prochaska & DiClemente, 1983, 1984), each intervention site distributed printed HIV prevention materials, condoms, and bleach kits. Preliminary findings indicated positive changes in consistent condom use for vaginal intercourse with a main partner and with other partners, consistent condom use for anal intercourse with other partners, and consistent use of bleach to clean injection equipment.

National Intervention Methods

National media campaigns have delivered small doses of HIV interventions (e.g., mailing of a brochure to all Americans), resulting in small behavior changes. In contrast to media campaigns, social marketing campaigns deliver intensive interventions (e.g., media and advertisements) to subgroups at high risk. These programs are usually evaluated by comparing preexisting levels of behavior prior to the campaign and monitoring behaviors over time.

To date there have been 47 evaluations in 16 countries of national media campaigns, only four of which would be classified as social marketing programs. The programs have generally been media interventions directed toward the general population and have varied substantially in dose, message, and

evaluation procedures. Some programs have evaluated attitudinal changes in the population (n=9), others have examined knowledge of prevention strategies for HIV (n=12), and a few have evaluated behavior (n=11). Within each type of evaluation, approximately two-thirds of the programs have demonstrated a positive outcome. Those without positive outcomes have not found negative results, but instead found no differences. Only five programs have monitored behavioral changes over time associated with their national programs.

In 1986, the Swiss government introduced one of the better campaigns—a three-tiered HIV prevention intervention that provided (1) HIV education of the general population; (2) HIV prevention messages targeted at high-risk adolescents, drug users, and homosexuals; and (3) individual counseling with providers. Over 10 years, knowledge about AIDS has increased, without the development of fear or stigmatization, and condom use has increased with casual partners, those with multiple partners, and new steady partners by about 20 percent across age groups; the rate of sexual activities did not change. Similar support for behavioral change can be found in data from France, Germany, the Netherlands, Scotland, Sweden, the United Kingdom, and the United States, but with generally lower rates of behavioral change (Dubois-Arber et al., in press).

Future Directions

Four areas for further research should receive high priority:

- Intervention studies with heterosexual men and women that have sufficient sample size to detect a difference in biological outcomes and with followup of sufficient duration.
- Intervention programs tailored for heterosexual men.
- AIDS prevention programs for seropositive persons and serodiscordant couples.
- Studies of prevention programs for vertical HIV transmission, particularly decisionmaking and ways of enhancing the rate of testing and adherence to medication during pregnancy, are urgently needed.

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Behavioral Interventions With Women

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Introduction

In the 14 years since AIDS was first recognized in the United States, it has become one of the most devastating public health threats of this century. Despite the fact that transmission routes of HIV are well documented and generally well known, incidence of AIDS continues to rise in various population groups. AIDS among women continues to disproportionately affect ethnic minorities, primarily in the northeast and southern urban areas. Last year, 76 percent of women diagnosed with AIDS were Black and Hispanic (16 and 7 times higher rates than for white women, respectively) (CDC, 1996.).

AIDS incidence is rising at particularly alarming rates among women, who are the fastest growing subgroup of AIDS cases (Ehrhardt, 1996). The proportion of AIDS cases among women aged 13 and older has increased steadily since 1983, tripling between 1985 and 1994 (MMWR, 1995). In 1995, women accounted for 19 percent of all new AIDS diagnoses (CDC, 1996). The median age for women reported with AIDS diagnosis in 1995 was 35, with women aged 20–44 accounting for 81 percent of all female cases diagnosed in 1995 (CDC, 1996).

Among women diagnosed with AIDS, heterosexual transmission as the identified exposure source has more than doubled from 1983 to 1995, rising from 14 percent to 38 percent of cases (CDC, 1996). Of women initially reporting no risk exposure but who were later reclassified after further investigation, most (66 percent) had heterosexual contact with an at-risk (e.g., bisexual) partner (MMWR, 1995). Furthermore, CDC rates of heterosexual transmission may represent a lower bound estimate of this risk, as women who meet any other risk criteria are classified into that risk category.

Conclusions

There has been remarkable progress since the first two preliminary evaluations of HIV intervention targeting sexual adult at-risk women appeared in 1989 (Gibson et al., 1989; Vogler et al., 1989). It is encouraging that interventions have targeted a wide range of women that go beyond traditional risk groups. Based on the evidence reviewed, we conclude that HIV prevention programs, particularly when targeting women directly, focusing on behavioral skills, and involving multiple, sustained contacts, can be effective in changing sexual risk behavior in women. There also is evidence that community-level interventions hold promise for reaching and effecting change in women who may not be reached by more traditional research approaches.

Primary Prevention of HIV Transmission

This presentation reviews published reports on primary prevention of sexual transmission of HIV with women from the beginning of the AIDS epidemic through March 1996. All reviewed interventions were conducted in the United States, Canada, or Puerto Rico; these interventions described a psychological, behavioral, or educational component specifically to address sexual risk reduction and included a behavioral evaluation component. Manual and computer searches identified 47 studies that targeted women and provided a female-specific analysis of intervention effects. Sixteen of the 47 studies fulfilling more rigorous methodological reporting standards were considered separately.

Overall, the findings demonstrate that HIV prevention programs can be effective in reducing risky sexual behavior among at-risk women (Hobfoll et al., 1994; Hobfoll et al. 1994). Program effectiveness varied by intervention type, session, duration, and whether studies included women alone or both men

and women. The most efficacious HIV prevention programs were specifically directed toward women, focused on relationship and negotiation skills, and involved multiple, sustained contacts (Kelly et al., 1994). Evidence also indicated that community-level interventions hold promise. This review includes a methodological critique, identification of research gaps, and recommendations for future intervention research with women (Ehrhardt et al., 1995).

Several general conclusions merit further discussion. First, as just mentioned, gender specificity appears to increase the likelihood of finding positive intervention effects. It may be that in studies where women are not specifically targeted, one-on-one counseling approaches produce greater change because they can be tailored to women's individual and gender-specific issues that impinge on condom negotiation and use. Women in mixed intervention groups may be at a disadvantage when competing with men for participation time, particularly when they are outnumbered (which was the case in all but two studies that included both genders and employed a group intervention format). It is also possible that, where men outnumber women, female-specific concerns about condoms (including the threat of losing relationships or abuse) take a back seat to men's concerns.

Future Directions

Until such time as cost-effective, community-level interventions are empirically demonstrated to be effective in evoking sexual risk reduction, interpersonal interventions continue to be the best strategy against HIV risk behavior. However, for this type of intervention to be effective, it is critical that a minimum number of sessions be conducted and relational skills addressed. Without adequate relational skills training, widespread behavioral changes will be impeded by women's risk for abuse or abandonment if condom use is suggested. It is also important that the interpersonal interventions are gender-specific and culturally sensitive. Cultural norms for "appropriate" gender role behavior that place a priority on fulfilling partners' needs and letting men lead sexually may further impede women from implementing changes. Innovative approaches must take into account issues of power discrepancies between women and their partners in the sexual negotiation process itself and in the broader context of their relationships with partners.

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Behavioral Interventions with Heterosexual Adolescents

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Introduction

A growing body of evidence indicates that behavioral interventions can reduce HIV risk-associated sexual behavior among adolescents. HIV/AIDS education programs taught by teachers in schools can reach most adolescents. However, HIV/AIDS education programs are also needed in community settings. Such programs can reinforce messages provided in schools, can reach adolescents who do not attend school, and can be tailored to the needs of high-risk adolescents. This presentation considers results of studies testing effects of behavioral interventions for adolescents that have been implemented in schools and in community settings, including medical clinics, shelters, and community-based organizations. It summarizes the risk of HIV infection among adolescents, key findings of intervention studies, and characteristics of effective interventions.

Although adolescents represent less than 1 percent of the cumulative total reported AIDS cases in the United States, adolescents are at risk of sexually transmitted HIV infection. About 18 percent of reported AIDS cases involve young adults 20–29 years of age. Many of them were infected during adolescence, because about 10 years typically elapse between infection with HIV and an AIDS diagnosis. Rates of unintended pregnancy and sexually transmitted diseases (STDs) also suggest an elevated risk of sexually transmitted HIV infection among adolescents. Moreover, although condom use has increased substantially since 1982, large percentages of adolescents still fail to use condoms consistently and are having coitus with many partners.

Conclusions

The presentation will conclude that studies conducted with adolescents demonstrate that interventions can significantly affect HIV risk-associated sexual behavior, including condom acquisition, condom use, unprotected sexual intercourse, frequency of sexual intercourse, and number of sexual partners. These behavioral changes have been demonstrated across several venues: schools, medical clinics, weekend programs, homeless shelters, and community-based organizations. This body of research supports the view that effective interventions (a) are tailored to the study population or culture based on formative research with members of the study populations and (b) have an explicit theoretical basis. A strength of this research is that it considers not only the effectiveness of these interventions in changing behavior, but also theoretical mechanisms, such as the variables hypothesized to mediate intervention effects. Significant behavioral effects seem to be due to changes in HIV risk-reduction knowledge, outcome expectancy, self-efficacy, skills, and behavioral intentions induced by the interventions.

Reducing the Risk of HIV Among Adolescents

Interventions to reduce adolescents' HIV risk-associated behavior face several formidable challenges. Adolescents often feel invulnerable and do not perceive themselves to be at risk. It may be difficult to persuade adolescents to practice abstinence if they have decided to be sexually active. Adolescents may hold negative beliefs about safer sex practices, including the belief that condoms adversely affect sexual enjoyment. They may lack the confidence to negotiate safer sex. Even if an intervention successfully surmounts these obstacles, it may not have detectable effects on sexual behavior if that behavior is sporadic, which is often true of young adolescents.

Several well-controlled studies have documented significant effects of interventions on adolescents' HIV risk-associated behavior, including condom acquisition, condom use, unprotected sexual intercourse, frequency of sexual intercourse, and number of partners. Approaches based on formative research with members of the study population and on a solid theoretical framework are most effective in changing HIV risk-associated behavior. By measuring the theoretical mediators of intervention-induced behavior change, a better conceptual understanding of risk behavior has emerged. Social cognitive theory, the theory of reasoned action, the health belief model, and theories that build on them are the most commonly used theories. These theories highlight the importance of beliefs, outcome expectancy, perceived norms, skills, self-efficacy, and intentions as determinants of HIV risk-associated behavior.

Review of Research Questions and Studies

Intervention studies have addressed several important questions about research with adolescents: Can behavioral skills be increased? Can behavior change be sustained at long-term followup? Can culture-sensitive interventions be effective when implemented by facilitators who do not belong to the same ethnic group as participants? Can interventions implemented by regular classroom teachers be effective? Can the behavior of high-risk populations be changed? This presentation will describe four of the studies that bear on these questions: one conducted at a health center, one that recruited from urban public schools for a weekend program, one implemented by regular classroom teachers in urban public schools, and one that recruited adolescents from a homeless shelter.

The first study tested an intervention to reduce risk of sexually transmitted HIV infection among 246 low-income African-American adolescents (mean age = 15.4 years) at a comprehensive health center (St. Lawrence et al., 1995). It considered whether behavioral skills could be increased and examined whether behavior change could be sustained at a long-term followup. The adolescents were randomly assigned to a single-session HIV education program or an 8-week HIV cognitive-behavioral intervention combining education and behavioral-skills training, including correct condom use, sexual assertion, refusal, self-management, problem-solving, and risk recognition. Data were collected preintervention and at 2, 6, and 12 months postintervention. About 92 percent of the adolescents took part in the intervention and postintervention assessments.

The study revealed several important effects of the theory-based intervention. Briefly, adolescents in the cognitive-behavioral intervention scored significantly better on an objective measure of behavioral skills than did those in the control condition. In addition, significant postintervention effects were found on HIV knowledge, response efficacy, and perceived self-efficacy; HIV risk-associated behavior was also affected. The skill-trained participants reported reduced unprotected intercourse, and the percentage of adolescents who initiated sexual intercourse was significantly lower among those in the skills training condition. The behavioral effects were sustained through the 12-month followup. This study demonstrated that behavioral skills were acquired, that intervention-induced sexual behavior change can be sustained over 12 months, and that the intervention did not encourage sexual intercourse, but delayed it.

The second study addressed the important question of whether it is possible for a theory-based, culture-sensitive HIV intervention to be effective when the race and gender of participants and facilitators are not matched or when the groups are not homogeneous in gender (Jemmott et al., 1996). Young inner-city African-American adolescents (mean age = 13.1 years) who volunteered for a program held on Saturdays were assigned randomly to a 5-hour HIV intervention or a 5-hour general health promotion control intervention and to a small group that was either homogeneous or heterogeneous in gender and led by a male or female facilitator who was African-American or white. The HIV intervention was based on social cognitive theory and the theory of reasoned action and on information gathered from formative research conducted with members of the study population. The intervention involved group discussions, videos, games, interactive exercises, and role playing designed

to influence (a) HIV risk-reduction knowledge, (b) behavioral beliefs about the consequences of condom use, and (c) behavioral skills and self-efficacy regarding refusal, negotiation, and condom use. In addition, it encouraged the adolescents to make proud and responsible decisions to protect themselves and their community.

The study had several important findings. The participants in the HIV intervention had greater HIV knowledge, more favorable behavioral beliefs about condoms, greater perceived self-efficacy, and stronger intentions to use condoms after the intervention than did those in the control condition. Six-month followup data collected on 93 percent of the original participants revealed that those who received the HIV intervention reported less HIV risk-associated sexual behavior, including unprotected sexual intercourse, than did their counterparts in the control condition. Self-reported sexual behavior and changes in self-reported behavior were unrelated to scores on a standard measure of social desirability response bias. Most important, tests of eight specific interaction hypotheses were nonsignificant. The effects of the HIV intervention were about the same irrespective of the race and gender of the facilitator, the gender of the participants, and the gender composition of the intervention group. This study demonstrates that risk behavior can be reduced among young adolescents and that the effects of a theory-based culture-sensitive intervention can generalize across implementation by facilitators of diverse races and either gender.

The third study tested effects of an HIV risk-reduction intervention implemented by regular classroom teachers in public high schools in New York City (Walter & Vaughan, 1993). The participants were 1,316 African-American, Latino, white, and Asian 9th and 11th grade students (mean age = 15.7 years). Students in two pairs of demographically similar high schools were assigned to receive a six-lesson HIV risk-reduction intervention or served as a comparison group. Three theories of health behavior change (i.e., the health belief model, social cognitive theory, and a model of social influence) guided the development of the HIV risk-reduction intervention. Formative research conducted with the target population identified deficiencies and problem areas in adolescents' knowledge, beliefs, self-efficacy, and behavior. The curriculum focused on conveying facts about HIV risk-reduction, fostering theoretically derived beliefs favorable to HIV risk-reduction preventive behaviors, and teaching skills necessary for the successful performance of AIDS preventive behaviors.

Three-month followup data collected on 72 percent of the original participants revealed significant effects of the intervention. The students who received the intervention scored higher in HIV risk-reduction knowledge, perceived susceptibility, beliefs about benefits of condom use, normative support for condom use, and self-efficacy than did those who did not receive the intervention. In addition, the students in the intervention group reported significantly less HIV risk-associated behavior than did those in the control condition. They reported fewer high-risk partners, more monogamy, and more consistent condom use. Moreover, none of the intervention effects were found to vary significantly by students' age, gender, or race/ethnicity.

The fourth study tested an intervention to reduce HIV risk-associated sexual behavior among runaways, a population at high risk of STDs (Rotheram-Borus et al., 1991). The participants were primarily African-American and Latino adolescents at two residential shelters in New York City. One shelter served as the intervention site, and the other as a nonintervention control site. The intervention consisted of twenty 90- to 120-minute sessions that addressed (a) HIV risk-reduction knowledge, (b) coping-skills training, (c) individual barriers to safer sex, and (d) access to health care and other resources important to the population. The activities included video and art workshops where runaways developed soap opera dramatizations, public service announcements, commercials, and raps about HIV prevention. The activities addressed many factors suggested by social cognitive theory. Hedonistic outcome expectancies were addressed by a focus on the use of condoms in a sensuous manner. Role playing, video workshops, dramatizations of soap operas, and practicing prepared scripts for handling interpersonal problems should strengthen self-efficacy to negotiate safer sex. Activities were used to build group norms of safer sex over time.

Adolescents at the intervention and nonintervention sites did not significantly differ on key demographic or sexual risk behavior variables. The intervention had significant effects on sexual behavior among the 77 percent of participants who took part in 3- or 6-month postbaseline interviews. Adolescents who attended a greater number of intervention sessions reported more consistent condom use, controlling for baseline self-reports. The number of intervention sessions attended also significantly predicted reductions in a high-risk pattern of sexual behavior at both followups. Thus, this study demonstrates effects of a carefully designed intervention on a key population—runaway and homeless youth—in a major AIDS epicenter.

Future Directions

Given the risk of sexually transmitted HIV among adolescents, the results of this body of research are encouraging: they suggest that carefully designed, theory-based interventions that take into account the characteristics of the particular population or culture can curb HIV risk-associated sexual behavior among adolescents in a variety of settings. Nevertheless, several issues merit investigation in future studies. There is a need for more studies on long-term effects of interventions on early adolescents or preadolescents. There is also a need for studies comparing the effects of different intervention strategies. Finally, there is a need for studies on the generalizability of intervention effects when the interventions are implemented by community-based organizations rather than university-based researchers.

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Community-Based Outreach Risk-Reduction Strategy To Prevent HIV Risk Behaviors in Out-of-Treatment Injection Drug Users

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Introduction

Infection with human immunodeficiency virus (HIV) in injection drug users (IDUs) is spread primarily through multiperson reuse of contaminated syringes/needles and other drug injection equipment as well as through unprotected sexual intercourse with infected individuals. The HIV epidemic in the United States is driven in large part by IDUs, their sex partners, and their offspring. Drug users constitute an important high-risk group in themselves, but they also have the potential to serve as a bridge for HIV transmission to non-IDUs. To date, the United States has had 548,102 cases of AIDS, with 36 percent (193,278 cases) attributed directly to IDU or indirectly through IDU sexual contact. Roughly half of all new HIV infections yearly (41,000) are among drug users (Holmberg, 1996).

IDUs are linked in a complex sequence of behaviors preceding injection (acquiring, preparing, and dividing the drugs) that increase the likelihood of multiperson reuse of drug injection equipment and other paraphernalia. During the early to mid-1980s, sharing patterns of IDUs were also influenced by the (1) increased availability of powdered (injectable) cocaine following years of heroin use by IDUs; (2) emergence of shooting galleries and anonymous sharing of contaminated needles and syringes; and (3) inaccessibility to sterile injection equipment (Alcabes & Friedland, 1995).

To limit the spread of HIV infection to IDUs, AIDS prevention has relied on outreach to IDUs in their communities to create multiple opportunities to reduce drug use, needle practices, and high-risk sexual behaviors. It is estimated that 50–85 percent of IDUs are not in treatment at any one time.

This presentation will first discuss the community-based outreach and HIV testing and counseling risk reduction model, which serves as the foundation for research on the prevention of HIV and HIV-related behaviors in out-of-treatment IDUs. Second, the literature on the efficacy of these community-based behavioral interventions to reduce HIV risk-taking and increase protective behaviors will be reviewed. The data are from two large-scale multisite community trials of the multicomponent HIV prevention strategy: (1) the National AIDS Demonstration Research (NADR) program (1987–1991) and (2) the Cooperative Agreement for AIDS Community-Based Outreach/Intervention Research Program (1990–present). In the 29-site NADR study, 36,000 IDUs received risk reduction interventions and in the 23-site Cooperative Agreement Program, about 14,000 IDUs have thus far been recruited.

Conclusions

AIDS prevention clearly has worked and continues to work with IDUs. Data from NADR and the Cooperative Agreement programs show that many IDUs report that they have changed their drug use patterns, needle practices, and sexual behaviors to reduce their risk of acquiring or transmitting HIV.

- Community-based outreach interventions are effective in facilitating behavior change among many IDUs. Outreach interventions consisting of risk-reduction information and referral to services, condom and bleach distribution, HIV antibody testing, pre- and posttest counseling, and demonstration and rehearsal of risk reduction skills (hereafter referred to as the "standard intervention") have helped IDUs reduce their risk-taking behaviors—particularly drug and needle using practices, and to a lesser extent sex risk behaviors—thereby reducing their risks for HIV infection.

- Some IDUs received only the standard intervention whereas others also received site-specific enhancements. In general, early findings suggest that exposure to enhanced interventions did not result in greater changes in risk behaviors than the standard intervention; however, some recent evidence indicates that intensive exposure to interventions may be associated with greater change.
- Some IDUs have stopped using drugs. Although many IDUs continue to use drugs, they have reduced their risk for HIV infection by eliminating or reducing their frequency of injection, as well as reducing the rates of multiperson reuse of potentially contaminated syringes and other drug injection equipment, increasing their rates of equipment disinfection, and increasing their condom use.

Community-Based Outreach and HIV Testing and Counseling Risk-Reduction Model

Over time, the standard intervention community-based model that combines street outreach with HIV testing and counseling has evolved as a feasible and effective way to engage the out-of-treatment population in AIDS prevention (Coyle, 1993). The model originated in Chicago in the late 1960s to respond to the drug epidemic with former addicts and provided targeted outreach to active IDUs to encourage them to enter methadone maintenance treatment (Hughes, 1977). The model was later adapted in the mid to late 1980s to respond to the emerging epidemic of HIV/AIDS in IDUs (Wiebel, 1993).

Beginning in 1987, the NADR and Cooperative Agreement programs adapted the standard intervention, which begins when outreach workers contact and engage IDUs. Outreach workers indigenous to the community act as credible messengers, provide risk-reduction materials and education, and arrange for IDUs to receive free HIV testing and counseling in private settings. Pretest counseling encourages HIV antibody testing; if test results are positive, posttest counseling refers IDUs to appropriate services. In addition, each site developed and implemented a site-specific enhanced intervention that was intended to reinforce the acceptance and promote the adoption of a hierarchical risk-reduction strategy.

A drug-related risk-reduction hierarchy promotes the following: (1) abstain from drug use; (2) if abstinence is not possible, stop injecting drugs; (3) if stopping drug injection is not possible, stop reusing injection equipment; and (4) if drug injection equipment syringes and needles continue to be reused, follow proper disinfection procedures.

There is also a hierarchy of sex risk-reduction options that encourages IDUs to (1) abstain from sex; (2) if abstinence is not possible, have nonpenetrative sex; (3) if sex is penetrative, use condoms and other barrier methods; and (4) reduce the number of sex partners.

Pre- and posttest counselors distribute bleach and help IDUs rehearse techniques for cleaning injection equipment; they also distribute condoms and teach their proper use.

Overview of Community-Based Strategies for IDUs

Twenty published studies from the NADR and Cooperative Agreement programs have evaluated the effectiveness of the standard intervention in facilitating changes in risk behaviors of IDUs, using single and multiple samples of IDUs (number of participants range from 103 to 2,973 IDUs). IDUs were located in their communities using targeted sampling, a strategy that provides the best possible sampling frames for street-based, hidden, and changing populations by mapping geographic areas of local drug use activity and HIV infection (Watters & Biernacki, 1989). Though not all research protocols of the two programs are identical (e.g., more HIV antibody testing and counseling occurred in the Cooperative Agreement and more intensive community-based outreach occurred in NADR), they are sufficiently comparable to support general statements and report cumulative findings across the studies.

IDUs were assigned to the standard intervention or to a standard intervention with a site-specific enhancement (more sessions beyond the standard intervention). Instead of having a “no-treatment” control, the standard intervention was always provided because it would be ethically unacceptable to withhold critical information for averting or managing HIV infection. Behavioral and serological data were collected at baseline and 6 months postintervention.

Generally, IDUs who received both the standard and the standard plus the enhanced interventions reduced their risks at about the same rate in NADR. (Preliminary results suggest that intensive enhancements may be more effective than standard ones [see, e.g., Booth, Crowley, & Zhang, 1996; Rhodes & Malotte, 1996]). The following summary of data from studies illustrates the magnitude of the change. Because different operational definitions of behaviors, the range and median are provided only for behaviors that were measured consistently.

Reductions in Risk Behaviors

- Decreased frequency of injection. (Measured in 14 studies; decreases were significant in 13. Range: 10–29.5 fewer injection events were reported per month. Median: 21.3 fewer injections/month.)
- Decreased multiperson reuse of injection equipment. (Measured in 10 studies; decreases were significant in 9. Range: 6.7–42.9 percent fewer reports of multiperson reuse of equipment in last month. Median: 14.3-percent reduction in multiperson reuse.)
- Decreased reuse of cookers and cotton. (Measured in six studies; decreases significant in all six. Range: 11.0–50.0 percent of IDUs stopped or reduced their reuse of cookers, cotton, and other drug injection equipment. Median: 20.1 percent reduced reuse.)
- Decreased use of shooting galleries or other group injection settings. (Measured in two different ways in six studies; decreases were significant in four.)
- Decreased risky needle practices. (Composite index variously constructed in six studies, involving, e.g., reuse of water, cookers, cotton, and number of shooting partners; decreases were significant in all six studies.)
- Decreased number of sex partners. (Measured in three studies; decreases were significant in one.)
- Decreased risky sex. (Composite index of risk measured in seven studies, involving, e.g., condom use, number and type of sex partner, and type of sex contact); decreases were significant in five.)

Increases in Protective Behaviors

- Increased needle disinfection. (Measured in seven studies, but measure was not consistent in operationalizing disinfection procedure; increases in disinfection were reported to be significant in five studies.)
- Increased entry into drug treatment. (Measured in four studies; increases were significant in four, although one showed that retention in treatment was not improved.)
- Increased use of condoms. (Measured in five studies in various situations; increases were significant in all five studies.)

Reductions in HIV Incidence

- Declines in prevalence of risk behaviors accompanied by declines in HIV incidence. (Measured in one study, which revealed significant reductions in risk and HIV incidence; see Wiebel et al., 1996, below for details.)

Examples of Effective Interventions

Multisite Analysis of Behavior Change

A study by Stephens et al. (1993) analyzed data from multiple NADR sites to examine the effects not only of the standard intervention but also of intervention exposure (e.g., the duration and content of community-based interventions delivered to out-of-treatment drug users). Data from 28 NADR sites showed significant postintervention reductions in injection frequency: the proportion of IDUs injecting daily declined from 45 percent to 24 percent for heroin, from 29 percent to 14 percent for cocaine, and from 29 percent to 16 percent for speedball (a drug cocktail combining heroin and cocaine). Moreover, 57 percent of postintervention IDUs were successful in reducing or maintaining low levels of “needle risk,” a composite of three variables measuring reuse of needles, number of persons with whom needles were reused, and use of new or disinfected needles. In addition, exposure time in the intervention was a significant predictor of reduced injection frequency (or continued low frequency) among heroin, cocaine, and speedball injectors. Finally, three intervention components were found to be significant predictors of low or reduced injection frequency (i.e., provision of bleach and condoms, number of demonstrations or rehearsals of bleach and condom use, and number of group intervention/education sessions).

Intervention Effectiveness, Risk Behavior, and Seroincidence

Another NADR study used HIV seroincidence as an outcome measure (Wiebel et al., 1996). Investigators collected six waves of data from targeted networks of IDUs who were given HIV testing and counseling and exposed to intensive community outreach over a 4-year period. Results showed a significant decrease in the rate of new infections among IDUs (n=641) exposed to the intervention from 1988 to 1992 (seroconversion declined from 8.4 per 100 person-years at wave 1 to 2.4 per 100 person-years in waves 5 and 6). The only variable associated with seroconversion was “injecting risk,” which was defined as reuse of dirty needles or sharing cookers, cotton, or water. The IDU cohort contacted in the outreach program was compared with a group of IDUs who had not been exposed to the intervention. At the final followup, 14 percent of postintervention IDUs continued injecting risk, which was significantly less than the 50 percent of nonintervention IDUs who continued to practice injection risks.

Future Directions

Despite substantial progress in AIDS prevention with IDUs, unacceptably high numbers of new HIV infections are occurring in IDUs and their sex partners, and many IDUs are engaging in high-risk practices.

Interventions that are responsive to the changing dynamics of the epidemic and the accumulating knowledge base continue to be an urgent need. Combinations of interventions (e.g., community-based outreach, needle exchange programs, drug treatment as HIV prevention) should be developed to reach IDUs who have been exposed to a range of interventions but have not yet been able to change their behaviors. Interventions are also needed to help IDUs who have made changes in their behaviors, sustain those changes and limit and/or eliminate their risks of acquiring HIV infection. Noninjecting crack-smokers who are at extremely high risk for HIV infection need AIDS prevention efforts designed

specifically for their risk patterns. Finally, methodological challenges associated with field-based research related to the prevention of HIV in IDUs and other populations at risk must be addressed.

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Role of Needle Exchange Programs in AIDS Prevention

David Vlahov, Ph.D.

Introduction

Injection drug users (IDUs) are at high risk for human immunodeficiency virus (HIV) and other blood-borne diseases (Esteban, 1993; Levine et al., 1995; Des Jarlais et al., 1992). In the United States, IDUs account for nearly one-third of the cases of AIDS; either directly or indirectly (i.e., heterosexual and perinatal cases of AIDS where the source of infection was an IDU) (Alcabes & Friedland, 1995). IDUs also account for a substantial proportion of cases of hepatitis B (HBV) and C (HCV) virus infections (Levine, Vlahov, & Nelson, 1994). The primary mode of transmission for HIV among IDUs is parenteral, namely through direct "needle sharing" or multiperson use of syringes (Nicolosi et al., 1992; Selwyn et al., 1987).

Despite high levels of knowledge about risk, multiperson use of needles and syringes is due primarily to fear of arrest and incarceration for violation of drug paraphernalia laws and ordinances that prohibit manufacture, sale, distribution, or possession of equipment and materials intended to be used with narcotics (Koester, 1994; Mandel et al., 1994). Under these laws, it is possible to obtain hypodermic syringes and needles with a medical prescription. In 45 states and the District Columbia, such laws are in effect and severely limit the availability of drug paraphernalia. In 1986, the Federal Government enacted a statute to further limit the availability of drug-related equipment.

Needle exchange programs were originally set up to reduce blood-borne infections among IDUs. These programs have become an integral component of comprehensive HIV prevention programs in many countries (e.g., Amsterdam). More than 100 needle exchange programs have been established in the United Kingdom and Australia (Stimson et al., 1988).

Needle exchange programs in the United States date back to 1986, and it is estimated that in 1996 there are approximately 100 needle exchange programs in North America (David Purchase, North American Syringe Exchange Network, personal communication). In part, because of the ban on the use of Federal funds for the operation of needle exchange, it has been difficult to evaluate the efficacy of these programs. This review will present data from the studies that have evaluated the role of needle exchange programs in AIDS prevention.

Conclusions

The aggregated results support the positive benefit of needle exchange programs and do not support negative outcomes from needle exchange programs.

- When legal restrictions on both purchase and possession of syringes are removed, IDUs will change their syringe-sharing behaviors in ways that can reduce HIV transmission.
- Needle exchange programs do not result in increased drug use among participants or the recruitment of first-time drug users.

Overview of Needle Exchange Studies

Evidence for the efficacy of needle exchange programs comes from three sources: (1) studies originally focused on the effectiveness of needle exchange programs in non-HIV blood-borne

infections; (2) mathematical modeling of data on needle exchange on HIV seroincidence; and (3) studies that examine the positive and negative impact of needle exchange programs on HIV/AIDS.

Needle Exchange Programs with Blood-Borne Diseases

In 1984, Amsterdam established a needle exchange program that was originally designed to limit transmission of the HBV (Bunning, 1991). Case-control studies have provided powerful data on the positive effect of needle exchange programs on reduction of two blood-borne viral infections (HBV and HCV). For example, a case-control study in Tacoma, Washington, showed that a sixfold increase in HBV and a sevenfold increase in HCV infections in IDUs were associated with nonuse of the needle exchange program (Hagan et al., 1994).

Mathematical Modeling of Needle Exchange on HIV Seroincidence

The first federally funded study of needle exchange was an evaluation of the New Haven needle exchange program, which is legally operated by the New Haven Health Department. Rather than relying on self-report of reduced risky injection drug use, this study utilized mathematical and statistical modeling, using data from a syringe tracking and testing system. Incidence of HIV infection among needle exchange participants was estimated to have decreased by 33 percent as a result of the needle exchange program (Kaplan & Heimer, 1995). Because demographic and behavioral data were collected at the time of recruitment, it was possible to relate individual client characteristics (e.g., age, injection frequency, frequency of needle sharing) to spread of HIV. For example, the mean age (approximately 33–34 years old) and duration of infection (men = 10 years; women = 5–10 years) did not change during this study. Women tended to remain stable at 20 percent of participants, but the percentage of whites participating increased. In the beginning, 83 percent of the participants were nonwhite, and the infection rate in the syringes was 67.5 percent; after 7 months those figures had changed to 67 percent nonwhite and the infection rate in the syringes to 43 percent.

Positive and Negative Impact of Needle Exchange Programs

Needle exchange programs have been established to increase the availability of sterile injection equipment and to remove any contaminated needles from circulation. The following positive outcomes have been used to evaluate the efficacy of needle exchange programs: (1) reduction in high-risk behavior, (2) reduction in HIV infection rates, and (3) increased referral to drug treatment programs.

Needle exchange programs are not universally praised because of concern about negative outcomes. There is a concern that publicly supported needle exchange programs will condone drug abuse and undercut efforts to get IDUs into drug treatment programs and off drugs. The following are possible negative outcomes: (1) possible increase in drug use; (2) increase in first-time drug users; and (3) increase in inappropriate disposal of contaminated syringes.

A series of Government-commissioned reports have reviewed the data on positive and negative outcomes of needle exchange programs. The major reports are from the National Commission on AIDS (National Commission on Acquired Immune Deficiency Syndrome, 1991); U.S. Government Accounting Office (U. S. General Accounting Office, 1993); the Centers for Disease Control/University of California (Lurie et al., 1993); and the National Academy of Sciences (Normand, Vlahov, & Moses, 1995). The latter two reports will be used in this review.

Reduction in High-Risk Behavior

Although none of the studies on needle exchange have been randomized, controlled trials, research results from evaluations have shown favorable reductions in risky drug-using behavior. Lurie and colleagues (1993) reviewed the 16 studies that have been conducted; 14 evaluated the impact of needle

exchange programs on the sharing of syringes—10 demonstrated decreases in sharing and 4 showed no change.

Watters and colleagues (1994) examined risk behaviors in IDUs over a 6_-year period in 13 cross-sectional surveys between 1986 and 1992. Among IDUs who reported sharing needles, the proportion of those reporting ever having used bleach increased from 3 percent in 1986 to 89 percent by 1988 and remained stable through 1992. Sexually active heterosexual male injectors also reported significant changes in condom use (i.e., IDUs reported using a condom 4.5 percent of the time in 1986, compared with 31 percent of the time in 1992).

In 1984, Des Jarlais and colleagues determined that 65 percent of IDUs reported having used shooting galleries in the preceding 2 years; in the 1990–1992 period, only 3 percent reported injecting in shooting galleries in the preceding 6 months.

Reduction in HIV Infection Rates

Data on long-term impact of needle exchange programs are sparse and have limited power. In five cities (Glasgow, Lund, Sydney, Tacoma, and Toronto), aggressive multicomponent AIDS prevention programs, including needle exchange, were vigorously implemented. There is well-documented evidence that the seroprevalence remained less than 5 percent for at least 6 years (Des Jarlais et al., 1992).

An analysis from a New York City needle exchange program concluded that there is a protective effect of needle exchange programs on HIV seroincidence (Des Jarlais et al., 1996). Watters and colleagues (1994) conducted a study to evaluate the effects of an all-volunteer syringe exchange program on risky injection drug use. Both studies reported a stabilization of HIV seroprevalence rates that coincided with increased reporting of risk-reduction activities.

Hagan and colleagues (1994) used a cross-sectional study of needle exchange participants that had a 2-percent HIV prevalence rate, which compared favorably with the 8-percent HIV prevalence rate among nonparticipants in the needle exchange program.

There is a discrepancy in seroincidence studies between needle exchange programs in the United States and Canada (Bruneau et al., 1996). In the U.S. studies, the comparison groups tend to be IDUs without access to sterile needles, whereas in the Canadian studies the comparison groups tend to include IDUs with access to needles from pharmacies. If the subset that is denied access are indeed riskier IDUs, and these individuals go to needle exchange programs, the result is a selection bias for U.S. research.

Increased Referral to Drug Treatment

Lurie and colleagues (1993) noted that 17 of 18 U.S. and Canadian programs provide referrals to drug treatment programs. Only six programs collect data on whether those referred actually enter treatment. Twenty-five percent of the participants in the New Haven needle exchange program requested drug treatment (Normand et al., 1995). It should be noted, however, that the effectiveness of referral to drug treatment programs is severely limited in the United States because of the few treatment placements available (Normand et al., 1995).

Increase in Drug Use

Lurie and colleagues (1993) identified eight studies that presented data on reported injection frequency. Three studies found reductions in injection drug use associated with needle exchange programs, four found mixed or no effects, and only one found an increase in injection compared with controls. This last one also found reduced needle sharing reported among needle exchange participants.

Increase in First-Time Injection Drug Users

Lurie and colleagues (1993) reviewed studies to determine when needle exchange programs would lead non-IDUs to become IDUs. The report indicated that the median age of participants in the programs was 33–41 years and the median duration of substance abuse was 7–20 years; this suggests that substance abuse predates participation in the needle exchange programs. A review of the experience in Amsterdam supported the fact that the programs did not lead to recruitment of drug abusers; the average age of drug users increased over time and the number of drug users under age 22 decreased from 14 percent in 1983 to 3 percent in 1988 (Normand et al., 1995).

Increase in Inappropriate Disposal of Contaminated Syringes

The report by Lurie and colleagues (1993) concluded that needle exchange programs do not increase the total number of improperly discarded syringes, and a surveillance project in Portland, Oregon, actually noted a decrease in the prevalence of discarded syringes near the program.

Future Directions

Future research in needle exchange should be focused in the following areas:

- Studies to clarify the impact of needle exchange programs on HIV seroincidence, especially when needles are available through pharmacies, should be conducted.
- Studies should be supported to identify the specific components of needle exchange programs that optimize the effectiveness of these programs.
- Research is needed to examine the interaction between needle exchange programs and risky sexual behavior, especially among hard-to-reach populations (e.g., youth and women).
- Because social networks are central to AIDS prevention efforts with IDUs, their role in the effectiveness of needle exchange programs needs to be studied.
- Epidemiological studies that monitor the long-term impact of needle exchange programs are needed.
- Methodological issues in needle exchange programs need to be carefully assessed. Although a randomized controlled trial might provide a definitive answer about the positive and negative outcomes of needle exchange programs, true random assignment may never be achieved. Therefore, sophisticated observational epidemiological designs urgently need to be supported on such a scale to answer important research questions about the efficacy of needle exchange programs (e.g., prospective and case-control methods).

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Drug Abuse Treatment as AIDS Prevention

David Metzger, Ph.D.

Introduction

The AIDS epidemic has had a profound impact on injecting drug users (IDUs) in the United States. Since the introduction of HIV into this risk group, more than 100,000 IDUs have died of AIDS-related causes, and it is estimated that more than 300,000 IDUs are currently infected with HIV. The epidemic has brought with it numerous attempts to reduce transmission through implementation of a range of interventions, including education regarding viral transmission and methods for reducing risk of infection; increased access to HIV testing and counseling; condom, bleach, and needle distribution; and expanded outreach. No intervention, however, has been as widely applied or as carefully evaluated as substance abuse treatment.

Typically, treatment programs are not considered to be prevention programs—treatment is usually applied when prevention fails. In the case of substance abuse treatment, however, there is real potential for treatment to achieve primary AIDS prevention goals, given the close association between drug use and HIV infection. By effectively treating drug use, direct and indirect risks of HIV infection can be reduced. A substantial literature points to the efficacy of drug and alcohol treatment in reducing substance use, and data from the past 10 years have clearly established an association between participation in treatment and lower risk of HIV infection.

Conclusions

Numerous studies have now documented that significantly lower rates of risk behaviors are practiced by drug users who are in treatment. This was the finding when in-treatment IDUs were compared with untreated IDUs, when drug use patterns during treatment were compared with pretreatment patterns, and when drug use patterns during treatment were compared with posttreatment drug use practices. Importantly, these self-report behavioral differences are consistent with seroprevalence and seroincidence data.

Despite the convergence of these findings, many would claim that without randomized controlled clinical trials, the differences cannot be attributed unequivocally to the treatment process. We cannot, however, ethically consider the random assignment of drug-dependent individuals to no-treatment conditions. This would be not only unethical but also terribly cynical, given the available compelling data.

Risk Reduction and Treatment Involvement

Data supporting the relationship between treatment participation and HIV risk reduction are derived from two broad research approaches: (1) examinations of risk behaviors of IDUs in and out of treatment and (2) studies that have used serologic data from cohorts of drug users to evaluate the role of treatment in HIV infection. This presentation will summarize both approaches and discuss methodological challenges. Although most of the currently available data are derived from studies of methadone treatment—the modality treating most IDUs in the United States—several studies will be reviewed that point to risk reduction associated with treatment for alcohol and cocaine use.

Nowhere is the association more clearly articulated than in the data from a 3-year study that examined the drug use patterns of 619 IDUs (Ball and Ross, 1991). These IDUs were randomly selected from six methadone maintenance treatment programs in New York City, Philadelphia, and Baltimore. The investigators identified a clear pattern of drug use in which daily injection was nearly universal prior

to treatment entry. Following treatment entry, rapid reductions in injection were observed, and these continued for those who remained in treatment. For those who left treatment, daily injections increased from 29 percent prior to leaving treatment to over 80 percent within 1 year of treatment termination. Participation in treatment was found to be associated not only with reductions in injection drug use but also with needle sharing. These data highlight the ability of treatment to interrupt individual patterns of drug use associated with high-risk practices. They also point to the likelihood of relapse among those who do not remain in treatment.

More recently, Caplehorn and Ross (1995) reported the results of a survey of 1,241 IDUs recruited from the community in Sydney, Australia. The self-reported risk behaviors of those who were in treatment at the time of the interview were compared with those reported by an untreated subgroup who met inclusion criteria for methadone treatment. The authors identified a 50-percent lower rate of needle sharing among those who were in treatment when compared with the out-of-treatment subgroup. Importantly, however, this relationship disappeared when in-treatment subjects who had not injected during the prior month were excluded from the analysis. This finding is important for this discussion because it suggests that the observed reductions in risk can be attributed to the direct effect of treatment in stopping use as opposed to simply assisting addicts to inject more safely. It also reminds us that not all IDUs who are in treatment have been successful in reducing their drug use and risky behaviors. Consistent with other reports in the literature, knowledge of HIV and associated risk factors did not differ between the treated and untreated IDUs.

Similar findings have been reported by others, and the consistency of their results is notable. Abdul Quader and colleagues (1987) found that both the frequency of drug injection and injection in shooting galleries were significantly reduced proportionate to the amount of time spent in methadone maintenance treatment. In New Haven, 107 methadone-maintained IDUs and 314 IDUs who were not in treatment were surveyed regarding their risk behaviors. Frequency of injections were found to be 50–65 percent ($p < .001$) higher among the out-of-treatment subjects (Meandzija et al., 1994).

HIV Prevalence, Incidence, and Treatment Participation

A variety of “nonrandomized” experimental strategies have been used to examine the relationship between HIV prevalence and incidence and substance abuse treatment participation. These approaches have produced findings consistent with the self-report data from drug users in and out of treatment. For example, Moss and coworkers (1994) reported on the HIV incidence rates of 681 initially seronegative IDUs who returned for testing. Within this “repeat” subset of the original cohort of 2,351 subjects, methadone treatment was found to be a “major protective factor.” Those subjects with a year or more of methadone treatment at entry into the study had less than one-third the incidence rate found among subjects with less than 1 year of treatment. Similar findings regarding the protective effects of methadone treatment have been reported by investigators who retrospectively examined HIV serostatus as a function of past treatment participation (Novick et al., 1990).

In a case–control study nested within a prospective evaluation of 952 seronegative IDUs, 40 incident cases were matched to 40 subjects who remained seronegative (Serpelloni et al., 1994). In analyses directed at identifying differences between cases and controls, duration of methadone treatment and methadone dosage were found to have dramatic protective effects. For every 3 months spent out of treatment, the risk of getting infected with HIV increased by 70 percent. The higher the methadone dosage, the lower the risk of infection. In multivariate analyses, these variables remained the most salient characteristics in explaining differences between cases and controls.

In Philadelphia, a prospective longitudinal study of HIV infection and risk behaviors among in- and out-of-treatment drug users was initiated in 1989 (Metzger et al., 1993). In this study, 152 IDUs were randomly selected from a methadone treatment program, and 103 out-of-treatment IDUs were recruited using a chain referral technique. Consistent with prior work, this study found significantly lower rates of

needle sharing, injection frequency, shooting gallery use, and visits to crack houses among the methadone-maintained IDUs.

At entry into this study, 18 percent of the out-of-treatment subjects and 11 percent of the methadone-maintained clients tested positive for antibodies to HIV. After 18 months of study, 33 percent of the out-of-treatment cohort were infected, whereas 15 percent of the methadone clients tested positive ($p < .01$). The incidence of new infection was strongly associated with participation in methadone treatment. When incidence rates were examined in relation to whether the subjects remained in treatment, changed their treatment status, or remained out of treatment, dramatically different rates of incident HIV cases were observed. Those who remained out of treatment were nearly six times more likely to have become infected than were those who remained in treatment during the first 18 months of the study. Among those who remained in methadone treatment for the entire 18-month study period, 3.5 percent became infected. Among those who remained out of treatment, 22 percent became infected with HIV (Metzger et al., 1993).

It could be argued that those individuals who seek and enter drug treatment are “by nature” more likely to practice safer behaviors than those who do not enter treatment; however, the data do not provide strong support for such an interpretation. The findings presented here indicate that both pre- and posttreatment drug use behaviors are dramatically elevated when compared with behaviors during treatment. Investigators have also identified a “dose–response” relationship between treatment duration, intensity, and methadone dosage and participation in risk behavior. Thus, although methodological challenges may serve a useful purpose in encouraging more rigorous research, they should not prevent us from forming well-reasoned conclusions based on the preponderance of evidence.

A final note on the prevention potential of substance abuse treatment programs. In addition to the direct delivery of drug treatment, these programs have had an important role in the implementation of many other prevention initiatives. As one of the few organized social institutions with access to drug users at risk of HIV infection, treatment programs have in many ways become community-based “staging areas” for risk reduction interventions directed at IDUs. Awareness is growing that individuals who are in treatment provide access to a much larger community of drug users who are not in treatment. Similar to the disproportionate impact of even a partially effective vaccine, significant preventive impact is possible through the effective treatment of drug users who are in treatment, even though they represent only a minority of all active drug users.

Future Directions

Unfortunately, funding for the support of substance abuse treatment programs has eroded during the course of the AIDS epidemic. There are now fewer treatment programs available and, within programs, fewer services. Thus, to maximize the preventive potential of drug and alcohol treatment, it will be necessary to first establish funding mechanisms that allow for an expansion of the treatment system and provide a stable base for program operations. At the same time, it is important to continue to investigate the “active ingredients” of substance abuse treatment and to increase research attention on those factors associated with treatment entry and retention.

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International Epidemiology of HIV Among Injecting Drug Users

Don C. Des Jarlais, Ph.D.

Introduction

The injection of illicit psychoactive drugs has now been reported in 120 countries throughout the world, and HIV infection among injecting drug users (IDUs) has been reported in 82 different countries. HIV infection among IDUs is truly an international pandemic, and much can be learned from cross-national comparisons of the spread of HIV among IDUs (Des Jarlais et al., 1992).

Conclusions

The international epidemiology of HIV infection among IDUs shows stark contrasts: areas that experienced explosive spread of HIV among local populations compared to areas where HIV infection rates have remained low and stable for long periods of time (Des Jarlais et al., 1995). A wide variety of intervention programs have been associated with behavior change among IDUs, and behavior change has been associated with lower rates of HIV infection. The key components of effective interventions appear to include implementing prevention efforts early, establishing trust between healthcare workers and IDUs, and providing IDUs with the means for behavior change.

Transmission

HIV has spread extremely rapidly among some populations of IDUs, with increases of 20–40 percent in HIV seroprevalence within a single year. Historical reconstructions of these epidemics indicate three common factors associated with very rapid spread of HIV among IDUs (Des Jarlais et al., 1992):

- Lack of AIDS awareness. IDUs in the area either were not aware of AIDS, or if aware of AIDS, did not perceive it as a local threat, believing instead that it affected other groups or IDUs in other areas.
- Practical scarcity of injecting equipment. Access to sterile injection equipment was limited by laws restricting sales and possession of injection equipment and/or by police practices of arresting or harassing persons found to be carrying drug injection equipment.
- Mechanisms for rapid, efficient mixing within the IDU population. Drug injecting in locations such as shooting galleries, dealers' places, central gathering places, and prisons facilitated "sharing" of injection equipment with large numbers of other IDUs on an almost random basis.

Behavior Change

A very large, diverse number of HIV prevention programs have been implemented to reduce HIV risk behavior among IDUs, including information only programs, community outreach programs, bleach disinfection programs, expanded drug abuse treatment, condom distribution programs, syringe exchange programs, and syringes through pharmacy sales programs. Almost all evaluation of HIV prevention programs for IDUs have shown self-reported risk reduction (primarily in injection behavior) associated with participation in the programs.

The self-reported risk reduction raises questions about the validity and the importance of these behavior changes. For example, are the self-reports valid, or are they primarily a function of social desirability (telling the interviewer what he or she is believed to want to hear)? Even if the self-reports are valid, are the behavior changes of sufficient magnitude to provide an important protective effect

against HIV infection? Studies from Bangkok, Thailand, and recent data from the World Health Organization Multi-Centre Study of AIDS and Injecting Drug Use indicate that the self-reported behavior changes are both valid and protective (Des Jarlais et al., 1996). IDUs who report that they had changed their risk behavior in response to the threat of AIDS were approximately half as likely to become infected with HIV than were IDUs who reported that they had not changed their behavior.

Future Directions

Research studies are needed to address the continuing international spread of injecting drug use (Des Jarlais et al., 1992). Studies of the political and community barriers to the implementation of effective HIV prevention programs are also needed (Normand et al., 1995).

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International Perspective on AIDS Prevention Research

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Introduction

Most recent estimates from the World Health Organization (WHO) indicate that as of December 1996 some 29.4 million adults and children have been infected with HIV and 8.4 million of them have developed AIDS. Ninety percent of all infections occurring today are in developing countries. Despite these daunting numbers and the well-known fact that it is difficult to change well-established behaviors, there is increasing evidence, worldwide, that AIDS prevention is possible. Some of the available evidence from studies done outside the industrialized world is reported in unpublished (gray) literature, and little of it is derived from randomized controlled trials (RCTs).

Conclusions

Evidence from developing countries indicates that a combination of interventions undertaken at different levels (c.f., Coates) can effectively prevent HIV infection. Successful targeted interventions include promotion of safer sex behavior and treatment of sexually transmitted diseases (STDs) in high-risk groups. These interventions are most effective when applied early, with resources made available to sustain them. Equally important is the need for political courage to counter the barriers that deter their implementation.

Epidemiology of HIV Infection Worldwide

The epidemiology of HIV infection is that of a classical STD. Worldwide, half of all infections are in youth 15–24 years of age, and the average age of infection declines as the epidemic becomes more established, reflecting the entry of new susceptibles into the population. However, like other STDs, HIV can be spread parenterally and from mother to child. Although the percentage of infections transmitted through injecting drug use worldwide is relatively small (around 10 percent), this route has been the major means of introduction of HIV into all Asian countries that now have a major epidemic, as well as some countries in South America. Despite considerable delay in their implementation—mostly because of political constraints—harm reduction efforts have begun in a few developing countries, although information on their impact is limited. Although antiretroviral therapy is moderately effective in reducing perinatal transmission, there is little or no access to these drugs in many developing countries. Accordingly, infection in newborns can be most readily avoided by prevention of HIV infection in women.

Because the vast majority of HIV infections worldwide are sexually transmitted, international efforts in HIV prevention have placed greatest emphasis on this means of spread. In almost all settings, heterosexual transmission is the predominant mode of sexual spread.

Prevention of Sexual Transmission

The main approach to prevention of sexual transmission has been promotion of safer sex messages through a wide variety of channels along with provision of condoms. When properly used, condoms are virtually 100 percent effective in preventing HIV transmission, best evidenced in studies of discordant couples (de Vincenzi, 1994). The initial evidence for the effectiveness of this approach came from a number of small-scaled, uncontrolled (pre/post) observational studies undertaken in Africa in the late 1980s and early 1990s (Asamoah-Adu et al., 1994; Nguigi et al., 1988; Williams et al., 1992; & WHO/GPA/IDS, 1992). These studies demonstrated that promotional efforts using social networks can bring about a reported increase in condom use and/or a decline in STD rates in specific high-risk

populations, especially commercial sex workers and their clients. Similar studies were subsequently undertaken in other geographic regions (Ford et al., 1996; Pauw et al., 1996). At the same time, evaluation of condom social marketing efforts (e.g., in Zaire) demonstrated that it was possible to increase the sales of condoms in the general population 50- to 100-fold over a few years' time.

Beginning in the late 1980s, there has been acceptance that educational efforts directed toward safer sexual behavior should be accompanied by more effective treatment of STDs. Genital ulcer disease has been found to increase the risk of HIV transmission per sexual exposure 10 to 50 times for male-to-female transmission and 50 to 300 times for female-to-male transmission, (Hayes, Schulz, & Plummer, 1995) and nonulcerative STDs (chlamydia and gonorrhea) increase the risk two- to fivefold (Laga et al., 1993). A recently conducted RCT in rural Tanzania demonstrated a 42-percent reduction in HIV incidence after 2 years of followup as a result of improved STD care (Grosskurth et al., 1995). This RCT included training of primary health care workers in STD syndromic case management, making available effective antibiotics and promoting health care-seeking behavior by those infected. A very recently completed controlled trial in Malawi has demonstrated that antibiotics used for the treatment of gonorrhea and nongonococcal urethritis significantly reduce the HIV viral load in semen, providing further evidence of the importance of STD treatment in HIV prevention (Hoffman, 1996).

The impact of these two approaches—promotion of safer sexual behavior and STD treatment—has not been evaluated in a large-scale research study. However, a clinic-based intervention among a longitudinal cohort of female sex workers, carried out in Kinshasa between 1988 and 1991, which included condom promotion as well as monthly STD screening and treatment, demonstrated the intervention's potential impact, with HIV incidence decreasing 62 percent and regular condom use increasing sixfold during this period (Laga et al., 1993). A study under way in Calcutta is evaluating, through repeated cross-sectional surveys, an intervention among commercial sex workers that combines STD treatment at a small clinical facility located in a high-volume, red-light area with outreach activities to sex workers that include condom distribution, training in condom negotiation skills, and STD symptom recognition.⁹ During a 3-year period, condom use has increased from essentially 0 percent to 75 percent, incident syphilis rates have declined from 25 percent to 13 percent, and HIV prevalence has remained below 5 percent (while it is above 50 percent in red-light areas in Bombay and New Delhi) (O'Reilly et al., 1995). A similar study is being carried out in Abidjan.

In 1993, WHO estimated that condom promotion and STD treatment—along with sex education in schools, needle and syringe exchange, and blood safety programs—could avert half (about 9.5 million) of the projected adult infections to the year 2000 worldwide at an annual cost of \$1.5–2.9 billion. This would result in a savings, in direct medical costs alone, of between two and five times the Gross National Product per capita for each case of AIDS prevented (Berkley, Piot, & Schopper, 1994). HIV prevention with a strong STD treatment component is, thus, one of our most cost-effective public health interventions in low- and high-income populations. Its cost-effectiveness is greatest early in the epidemic when activities can be confined to those populations practicing particularly high-risk behavior and diminishes as the infection spreads into the general population (World Bank Development Report, 1993).

One intervention whose effectiveness in prevention requires further study is voluntary counseling and testing (VCT). Noncontrolled studies among discordant couples in Kigali (Allen et al., 1992) and Kinshasa (Kamenga et al., 1991) suggest that VCT is effective in increasing and maintaining condom use in this population. Its effectiveness when only one partner received VCT is less clear. A multisite RCT under way in four developing countries (two east African, one Caribbean, and one Asian) supported by UNAIDS and the WHO will hopefully provide more definitive information. Plans for marketing of home HIV sample collection tests and eventually home diagnostic tests further indicate the urgent need for information on the impact on sexual behavior of an HIV diagnosis with and without direct counseling.

Interventions at Different Levels

There is no doubt that persuasive behavioral interventions are essential to HIV prevention, but experience in other areas (e.g., injury control, smoking) has demonstrated that it is also important to identify interventions that remove structural and environmental barriers or constraints to protective action or, conversely, to erect barriers or constraints that prevent risk-taking (Sweat and Denison, 1995; Tawil, Verster, & O'Reilly, 1995). For example, various approaches to modifying economic determinants to reduce risk of HIV infection could be applied in commercial sex-work, either within the sex work setting (enforcing condom use), in communities where sex work exists (improving women's literacy and education), or on a national or regional scale (paying the cost for wives to live with their husbands at distant places of employment). Other examples include changes in national laws and regulations that place high taxes on condoms, prohibit radio and television advertising of condoms, or outlaw wife inheritance. Structural means should be found to meet the needs of women who must acquire more control over their sexual and reproductive lives. Except for the case of Thailand, studies of such approaches, especially to prevent sexual transmission, are few to date and are warranted in the interest of sustaining and broadening prevention efforts.

The Case of Thailand

The best evaluated effort of a nationwide program in a developing country has been that of Thailand, and it demonstrates the value of combining intervention approaches. In that country, where the commercial sex industry is well established, a mass condom promotional campaign was begun in the late 1980s and a 100-percent condom use program was instituted in brothels in northern Thailand in 1989 and in the entire country early in 1992. Antibiotics are also readily available for treatment of STDs. These together resulted in a more than sixfold increase in the percentage of sex acts with commercial sex workers in which a condom was used, from 14 percent before 1989 to over 90 percent in December 1994, with a concomitant decrease of 85 percent in male STD cases nationwide seen at government clinics and a decline in HIV prevalence in pregnant women and military conscripts by the end of this period (Hananberg et al., 1994; Rojanapithayakorn and Hanenberg, 1996). This impact has been most vividly demonstrated in northern Thailand, where there has been a significant decrease in HIV prevalence among military conscripts from 12.5 percent in 1991 to 6.7 percent in 1995 (Nelson et al., 1996).

The Case of Uganda

There have been recent reports of a 30 percent decrease in HIV prevalence among pregnant women seeking antenatal care in high-prevalence districts in Uganda (Asiimwe-Okiror et al., 1995). Prevalence diminished by 35 percent in young women aged 15–19 and 20–24 years. Studies in Kampala have shown that much of this decrease can be attributed to a decrease in the number of sexual partners and an increase in condom use in relations at risk. Other factors such as saturation of the pool of susceptible individuals, change in the infectiousness of HIV-infected persons, and a decrease in “mixing” of noninfected and infected persons as more of those infected have died may have also played a role. These changes were the result of many epidemiological factors and behavioral and structural interventions in Uganda.

Future Directions

The need for more social and behavioral prevention research internationally and particularly in developing countries is undeniable. More information is needed about individual, cultural, and cognitive differences in human sexuality and the relevance of social relationships, sexual networks, and substance abuse (particularly alcohol) on sexual risk-taking. In addition, more information is needed about maintaining long-term behavioral changes, using a combination of targeted interventions at different levels. Efforts are also needed to learn how to better overcome the denial and stigma that still

exist in many developing countries and their consequences, on an individual level, in high-risk behavior and failure to seek STD treatment, and on a national level, in governments not taking the political action required to mount effective prevention efforts. Such research should use rigorous study designs and methods, including RCTs when appropriate, taking into account ethical considerations.

Major constraints to carrying out interdisciplinary prevention research are the lack of trained scientists and insufficient financial support. A concerted long-term effort is required by industrialized nations to remove these constraints. The fact that the AIDS epidemic in the United States is becoming more and more like that in developing countries should provide impetus for support of research carried out jointly by scientists from the United States and abroad in both locations.

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